RAYAT-BAHRA UNIVERSITY
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University School of Pharmaceutical Sciences

Study scheme and Syllabus

Batch 2014

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	Advanced Pharmaceutical Analysis	4	0	0	4
2	PS6102	Core-I Advanced Drug Delivery systems	4	0	0	4
3	PS6103	Drug Regulatory Affairs and intellectual property Rights	4	0	0	4
4	PS6104	Elective-I Industrial Pharmacy & Pharmaceutical Validation	4	0	0	4
5	PS6105	Advanced Pharmaceutics Lab-I	0	0	6	3
6	PS6106	Advanced Pharmaceutical Analysis Lab	0	0	6	3
7	PS6107	Seminar-I	0	0	0	2
Total			**16**	**0**	**12**	**24**

Study Scheme for M.Pharm (Pharmaceutics)

Semester: 2nd

S. No	Subject code	Subject Name	L	T	P	Credits
1	PS6201	Core-II: Advances in Pharmaceutical Formulation & Development	4	0	0	4
2	PS6202	Core-III: Quality Control & Assurance of Pharmaceuticals	4	0	0	4
3	PS6203	Elective-II (a) Advanced Biopharmaceutics & Pharmacokinetics or (b) Bio-nanotechnology	4	0	0	4
4	PS6204	Research Methodology & Biostatistics	4	0	0	4
5	PS6205	Advanced Pharmaceutics Lab-II	0	0	6	3
6	PS6206	Seminar-II	0	0	0	2
Total			**16**	**0**	**6**	**21**

Study Scheme for M.Pharm (Pharmaceutics)

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	36	
Total			**0**	**0**	**36**	**8**

Study Scheme for M.Pharm (Pharmaceutics)

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				
3	PS7403	Viva Voce	0	0	36	36*
Total			**0**	**0**	**36**	**40**

- **Cumulative credit of 3rd and 4th semester**

M.Pharm (Pharmaceutics) I Semester Syllabus

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

1. Spectroscopic methods:
Theory, Instrumentations, chemical applications and structural elucidation by UV, IR,
^{1}H NMR, ^{13}C 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 and Supercritical Fluid Chromatography.

3. Thermal Analysis: Theory, Instrumentations and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA).

4. Calorimetric Analysis: Theory, Instrumentations, chemical applications and structural Elucidation, Differential Scanning Calorimetry (DSC), Isothermal titration Calorimetry (ITC)

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

6. Electron Microscopy: Introduction to Scanning Electron Microcopy and Travelling 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, Morril- 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. J.R. Dyer – Application of absorption Spectroscopy of Organic Compounds (Prentice
Hall, London).
5. C.N.R. Rao – Chemical Application of Infra-red spectroscopy. (Academic Press, N.Y.).
6. L.M. Jackmann and B.D. Sternhell – Application of NMR spectroscopy in organic chemistry (Pergamon Press, London.).
7. F.W. McLafferty- Interpretation of Mass Spectra.
8. R.J. Hamilton- Introduction to High Performance Liquid Chromatography.(Chapman and Hall, London).
9. J.W.Munson- Pharmaceutical Analysis- Modern methods –Part A and Part B (Marcel Dekker).
10. Introduction to Spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.
11. Analytical chem.., 2nd edition by Kellner, Mermet, Otto, Valcarcel Wiley ECH.
12. Ewing's Analytical Instrumentation Handbook, 3rd edition, edited by Jack Cazes, Marcel Dekker.
13. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical formulations (VBS Publishers, Delhi).
14. Pharmacopoeia of India.
15. United State Pharmacopoeia

16. British Pharmacopoeia
17. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers Delhi)
18. F. D. Snell and C. T. Snell- Colorimetric Methods of analysis (Van Nostrand Reinhold Company, N.Y.).
19. C.N.R. Rao – Chemical Application ofInfra-red spectroscopy.(Academic Press, N.Y.).
20. 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 Advanced Drug Delivery systems	4	0	0	4

1. Fundamentals of Controlled Release Drug Delivery:
Influence of drug properties and routes of drug administration on thedesign of sustained and controlled release systems.

2. Oral controlled drug delivery systems:
Formulation, fabrication and evaluation of various oral controlled drug delivery systems including gastro retentive, 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; micro spheres, liposomes & quality control.

4. Mucosal drug delivery models:
Buccal, sublingual, rectal, nasal, mucosal & vaginal drug delivery: Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

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. Bioavailability and Bioequivalence:
Biopharmaceutical classification of drugs, absorption of permeability and solubility limited drugs. Biowavers for bioequivalence studies, strategies to enhance bioavailability.

7. Vesicular Drug Delivery System:
Liposomes [composition, preparation, characterisation, stability, pharmacokinetics, clinical applications, production and scale up]; Niosomes [structure & classification, methods of preparation, properties, release behaviour, characterisation, pharmacokinetics & in-vivo evaluation, applications and toxicity]; Micro emulsion [structures, theories of formation, formulation consideration, factors affecting formation of micro emulsion, phase diagrams, characterisation, stability and application].

8. Particulate Drug Delivery System:
Microparticles: [Polymers used & their selection, general methods of preparation, characterisation, kinetics of release, evaluation of efficacy, applications; 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.

9. Site specific drug delivery system:
Active & passive targeting, resealed erythrocyte, monoclonal antibodies drug targeting particulate carrier system, specific drug delivery to targeted organs like brain & colon, freeze drying of parenteral, environmental controlled parenteral manufacturing.

10. Ocular Drug Delivery:

Ocular Topical Drug Delivery, Issues and Challenges, Drug Candidate Selection, Product Design Considerations, Product Optimization Considerations, Processing Considerations.

11. Protein & peptide drug delivery system:

Physical aspects, biochemistry of protein drug (structure, properties & stability-Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.); general methods of analysis of protein & peptide drugs, barrier to transport & pharmacokinetics, different route of delivery, practical considerations; importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability & regulatory perspective.

12. Regulatory consideration in controlled release:

Modification requirements to demonstrate safety, efficacy & controlled release nature.

RECOMMENDED BOOKS

1. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- 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
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, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. 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. Presentation and recording of stability data, determination of shelf life. Stability test equipment and recent developments in this area.
3. Documentation :
Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents.
4. 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.
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.
Patenting in India – Introduction, Patent legislation, 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 Novaritis 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: Requiremnts of patenting: utility, novelty, nn-obviousness, patent specification & claims, Patent imfringement 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 2006, 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. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.
8. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
9. USPTO and WIPO Guidelines.
10. Orange Book, ICH guidelines, Indian Patents Act
11. Country specific Regulatory Guidelines (available from internet)
12. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc
13. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
14. 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)The Scope of Preformulation Studies: Introduction, Preformulation Testing Criteria, Regulatory Requirements, Testing Systems, Solid-State Characterization, Transport Across Biological Membranes.

b) Dissociation, Partitioning and Solubility: Introduction, The Ionization Principle, Quantitative Structure–Activity Relationships, Partitioning, Measurement Strategies

c) Release, Dissolution, and Permeation: Introduction, Release, Assay Systems, The Biopharmaceutics Drug Classification Systems

d) Solid-State Properties: Introduction, Crystal Morphology, Polymorphism, High - Throughput Crystal Screening, Solvates, Hydrates, Amorphous Forms, Hygroscopicity, Solubility, Study Methods

e) Dosage Form Considerations in Preformulation: Introduction, Solid Dosage Form Considerations, Solution Formulations, Emulsion Formulations, Freeze-Dried Formulations, Suspensions, General Compatibility

f) Chemical Drug Substance Characterization: Introduction, Scheme of Characterization, Impurities, Good Manufacturing Practice

g) Characterization of Biopharmaceutical Drugs: Introduction, Preformulation Studies, Packaging and Materials, Physio-Chemical Characterization Tests, Design of Preformulation Studies Methods in material characterization.

h) Particle dimensions: Particle size and powder surface area, Particle shape and surface morphology.

i) Characterization of solid state structure: Spectroscopy in pharmaceutical analysis, X-ray diffraction, Solid-state nuclear magnetic resonance, Vibrational spectroscopy, Calorimetry in pharmaceutical analysis, Thermal analysis techniques, Isothermal microcalorimetry, Water vapor sorption, Microscopy, Density measurements.

k) 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

l) 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

m) 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. Advances in Industrial Process:

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 1995.
3. J.I. Wells, Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester (UK), 1998.
4. R. Berry and R. A. Nash, Pharmaceutical Process Validation, Marcel Dekker, N.Y. (1993)
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 2002, vallabh prakashan , Delhi.

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6105	Advanced 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 perform validation of UV Visible Spectrophotometer
3. To calculate equation r^2 value and λmax of Nimuslide in various solvents
4. To carry out solubility studies of given poorly soluble drug sample in various solvents
5. To determine partition coefficient of given drug sample by shake flask method
6. To study the degradation pattern of aspirin into salicylic acid with respect to effect of temperature time and pH
7. 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
8. To formulate and evaluate calcium alginate of beads by using salt addition method
9. To formulate and evaluate mucoadhesive buccal patches of given drug
10. Formulation and Evaluation of Transdermal patch of given drug
11. To formulate and evaluate liposomes of given drug
12. To formulate liposomal gel by introducing prepared liposome in gelling agent.
13. To formulate and evaluate microspheres of given drug by salt addition method
14. To formulate and evaluate microsuspension of given insoluble drug
15. Formulation and Evaluation of microemulsion of given drug
16. To formulate and characterise basic multiple emulsion
17. To formulate and evaluate nanoparticles of given drug
18. Formulation and Evaluation of *In Situ* Gelling Drug Delivery system for the treatment of Ocular Diseases of given drug
19. 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.
20. To determine the pharmacokinetic parameters by using given data of i/v bolus dose
21. To determine the pharmacokinetic parameters by using given data of oral dose

RECOMMENDED BOOKS
Same as Given in PS6102

M.Pharm (Pharmaceutics) I Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6106	Advanced 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, spectro-photometric(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 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 Advances in Pharmaceutical Formulation & Development	4	0	0	4

1.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.

2. Formulation and development of capsules

a. Hard gelatin capsules : Development of hard gelatin capsules as a dosage form . Manufacturing process and material used in the shell and the steps used in its manufacturing such as sorting, printing, size and shapes, sealing and self locking closures. 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.

c. Materials other than gelatin used for capsule formulation.

3. Spheronization

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

4. Formulation and development of liquids

Phase behaviour of surfactants in binary and ternery 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 parentral route

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

6. Quality Assuarance-: Importance of QA, Concept of quality control, quality assurance & total quality controls. Sources of variation, Quality control of raw materials & pharmaceutical process & finished products. Documentation concepts of statistical quality control.

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, 2000, Lippincot williams and wilkins.
4. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.
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 & Assurance of Pharmaceuticals	4	0	0	4

1. Quality control and Assurance technique: Basis concepts of Quality:- Developing qualityculture.
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 gods, 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. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India.
5. Improving Quality through Planned experimentation by Moen, Tata Mcgraw Hill.
6. Good Manufacturing Practices for Pharmaceutical; A Plan for total Quality Control, 4 th Ed, Sidney willing.

7. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
8. Pharmaceutical Process Validation; By F. R., Berory and Robert A. Nash
9. Impurities Evaluation of Pharmaceutical; Satinder Ahiya Marcel Decker.
10. Quality Control of Packaging material in the Pharmaceutical Industry: Kenneth Harburn, Marcel Dekker.
11. Juran's Quality Control Handbook J.M. Jupron.4th Ed. Good design practices for GMP Pharmaceutical facilities. Andrew A Signature, Marcel Dekker.
12. cGMP for Pharmaceuticals. Pharma. Med. Press, I st edition by Manohar H. Potdar

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6203	Elective-II: Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	4

1. Biopharmaceutics :

Review of physicochemical, pharmaceutical and physiological variables affecting drug absorption from gastrointestinal tract.

2. Protein Binding :

Theory of plasma protein binding and implications, elements of Scatchard, Klotz and Rosenthal analysis for computation of binding parameters, experimental techniques to determine protein binding with their merits and limitations, factors influencing protein binding, effect of binding on drug pharmacokinetics.

3. Compartmental pharmacokinetics :

Review of fundamentals, Terminology, Basics of kinetics of single and multiple dose administration following instantaneous and non-instantaneous routes, one and two compartment body model kinetics, limitations of compartmental analysis.

4. Non-compartmental Pharmacokinetic Modeling Approach :

Merits of model-independent non-compartmental approaches, definition and significance, statistical moments, AUC, AUMC and their determination using trapezoidal and log-trapezoidal techniques, MRT and its significance in pharmacokinetics, computation of statistical moments from plasma and urine data, cut-off error, MDT, MTT, MAT, problem solving.

5. Nonlinear Pharmacokinetics :

Definition, significance and applications with literature examples, recognition of non-linearity, computation of nonlinear pharmacokinetic parameters (Vm, Km, AUC, etc.) by single Michaelis Menten kinetics.

6. Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

7. Clinical 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.

8. Bioavailability and Bioequivalence Concepts :

Assessment of bioavailability from plasma and urine level data, design and analysis of bioequivalence trials, Crossover designs, bioavailability of oral and non-oral dosage forms, statistical analysis of bioavailability and bioequivalence, pharmacodynamic models, Federal perspectives.

9. ***In vitro-In vivo*** **correlations (IVIVC) :**

Concepts, Biopharmaceutical Classification Scheme (BCS), varied IVIVC approaches with applications and limitations, dissolution as a surrogate to bioavailability for immediate release and extended release formulations, Federal perspectives

BOOKS RECOMMENDED

1. J.G. Wagner, Fundamentals of Clinical Pharmacokinetics, Drug Intelligence Publications, Hamilton, III, 1975.
2. J.G. Wagner, Pharmacokinetics for the Pharmaceutical Scientist, Technomic, Pa, 1993.
3. L. Shargel, and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT, 1993.
4. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, NY
5. M. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, Lea & Febiger, Philadelphia.
6. R.D.Purves, "Optimum Numerical integration methods for the estimation of area under the curve (AUC) and area under the moment curve (AUMC)". J.Pharmac. Biopharma., 20 (3), 211-226,1992.
7. P.G.Welling, F.L.S. Tse and S.V. Dighe (eds*) Pharmaceutical Bioequivalence*, Marcel Dekker Inc. New York, USA 1991.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6203	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.Instrumentation and Principles: Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.

5.Gene cloning :

Introduction to gene cloning. Main steps of gene cloning, Gene cloning procedures, Restriction endonucleases, Isolation of DNA to be cloned (Creation and screening of gene library), Bacterial plasmids, Plasmid cloning vectors and isolation of plasmid with DNA inserts. Application of genetic engineering with special reference to the production of proteins of pharmaceutical significance such as insulin, human growth hormone & tissue Plasminogen activator (t-PA).

6.Immobilised enzymes :

Definition, advantages over soluble enzymes, different methods of immobilization, effect on the stability of the enzymes, potential applications and uses of immobilized enzymes, Kinetics of immobilized enzyme catalysed reactions and different parameters like temperature, pH, enzyme and substrate concentration which influence the velocity of a reaction.

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.

BOOKS RECOMMENDED

1. Molecular Biology and Biotechnology by Smith and Wood, 1991,Chapman and Hall, New York and London

2. A textbook of Industrial Microbiology by Wulf Crueger and Anneliese Cruegar, 2nd edition, Sinauer Associates, INC, Sunderland MA01375

3. Martin's Physical Pharmacy and Pharmaceutical Sciences by Patrick J. Sinko, Vth edition, Lippincott Williams and Wilkins by Patrick J. Sinko
4. J. Woodward (Editor), Immobilized cells and Enzymes, A Practical Approach, IRL Press.
5. E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
6. N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
7. D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
8. T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
9. V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley- Interscience: Hoboken.
10. S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific andcontrolled drug delivery" CBS Publishers and Distributors.

M.Pharm (Pharmaceutics) II Semester Syllabus

Sub code	Subject Name	L	T	P	C
PS6204	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.

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.

2. Experimental design:

Meaning, need, features, basic principle and important concepts of experimental design different types of research designs [before-and-after without control design, after-only with control design, before-and-after with control design, completely randomized design, randomized block design, latin square design, factorial design], crossover design and bioavailability / bioequivalence studies.

3. Descriptive Data Analysis:

What is statistics?, parametric and non-parametric data, descriptive and inferential analysis, the organization of data (grouped data distributions), statistical measures (measures of central tendency & measures of spread or dispersion) , normal distribution (normal & non normal distribution, interpreting the normal probability distribution, practical applications of the normal curve) , measures of relative position (standard scores : the Z score, the T Score, the percentile rank), measures of relationship [pearson's product-moment coefficient of correlation (r), rank order correlation (ρ), phi correlation coefficient (ϕ)], interpretation of a correlation coefficient [outliers, misinterpretation of the coefficient of correlation, prediction], standard error of estimate. Application of linear regression and correlation to analysis of standard curves and drug analysis.

4. Inferential data analysis:

Statistical inference, the central limit theorem, parametric tests, testing statistical significance [the significance of the difference between the means of two independent groups, the null hypothesis (H0), the level of significance], decision making [two tailed and one tailed tests of significance, degrees of freedom], a one sample Z test, student's distribution (t) [significance of 13 the difference between two small sample independent means], homogeneity of variance [significance of the difference between the means of two matched of correlated groups (nonindepndent samples), statistical significance of coefficient of correlation], one way and two way analysis of variance (ANOVA) , multiple regression and correlation, nonparametric tests [the chi square test (X2), the mann-whitney test], outliers and missing data, multiple comparisons [Bonferroni t-test, Student newman keuls, tukey test, dunnets test, dunn's test].

Comparison of dissolution various tablet formulations by two way ANOVA, comparison of three drug treatments at three sites by two way ANOVA.

Recommended Books: -

1. Research In Education- John V. Best, John V. Kahn 10thedition
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
PS6205	Advanced 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. Stability study testing of tablet dosage forms (Any two products)
6. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
7. To plot the ternary phase diagram in the formulation development of emulsion.
8. 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.
9. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
10. To prepare liposome and determine particle distribution and drug entrapment efficiency.
11. Optimization of designing of dosage forms by 3^2 factorial designs.
12. 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