GURU NANAK INSTITUTE OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

(An autonomous institute under MAKAUT)

M.PHARM SYLLABUS

Regulation 2020

2020-21

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Table : Course of Study for M. Pharm. (Pharmaceutics)

SEMESTER I

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
THEORY					
R20_MPT1061T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
R20_MPT1062T	Drug Delivery System	4	4	4	100
R20_MPT1063T	Modern Pharmaceutics	4	4	4	100
R20_MPT1064T	Regulatory Affair	4	4	4	100
PRACTICAL					
R20_MPT1965P	Pharmaceutics Practical - I	12	6	12	200
R20_MPT1966	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**700**

SEMESTER II

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
THEORY					
R20_MPT2061T	Molecular Pharmaceutics (NanoTech and Targeted DDS)	4	4	4	100
R20_MPT2062T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
R20_MPT2063T	Computer Aided Drug Delivery System	4	4	4	100
R20_MPT2064T	Cosmetic and Cosmeceuticals	4	4	4	100
PRACTICAL					
R20_MPT2965P	Pharmacognosy Practical - I	12	6	12	200
R20_MPT2966	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**700**

SEMESTER III

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
THEORY					
R20_MPT384T	Research Methods and Biostatistics	4	4	4	100
R20_MPT381	Journal Club	1	1	1	100
R20_MPT391	Discussion/Presentation	2	2	2	100
R20_MPT392	Research Work	28	14		100
Total		**35**	**21**	**7**	**400**

SEMESTER IV

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
R20_MPT481	Journal Club	1	1	1	100
R20_MPT491	Discussion/Final Presentation	3	3	3	100
R20_MPT492	Research Work	31	16		100
R20_MPT482	Co-curricular Activities	3	3	3	100
Total		**38**	**23**	**7**	**400**

Table - Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	23
Total Credit Points	96

REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

SYLLABUS

Semester I

PHARMACEUTICS

1ST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(R20_MPT1061T)

SCOPE

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

Objectives

After completion of course student is able to know about,

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

THEORY 60 Hrs

1. (a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs

(b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

(c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

(d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double 10 Hrs

resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

(a) Thin Layer chromatography
(b) High Performance Thin Layer Chromatography
(c) Ion exchange chromatography
(d) Column chromatography
(e) Gas chromatography
(f) High Performance Liquid chromatography
(g) Ultra High Performance Liquid chromatography
(h) Affinity chromatography
(i) Gel Chromatography

5. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

(a) Paper electrophoresis (b) Gel electrophoresis (c) Capillary electrophoresis
(d) Zone electrophoresis (e) Moving boundary electrophoresis (f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

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

(a) Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

(b) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

(c) TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

Drug Delivery System

(R20_MPT1062T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

THEORY 60 Hrs

1. (a) Sustained Release (SR) and Controlled Release (CR) formulations : Introduction & basic concepts , advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. 10 Hrs

(b) Polymers: introduction, definition, classification, properties and application

(c) Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals. 10 Hrs

3. (a) Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. 10 Hrs

(b) Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

4. Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 6 Hrs

5. Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. 10 Hrs

6. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. 8 Hrs

7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 6 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

3. Encyclopedia of controlled delivery, Editor - Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

5. S.P.Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)

2. Indian drugs (IDMA)

3. Journal of controlled release (Elsevier Sciences) desirable

4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS

(R20_MPT1063T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY 60 Hrs

1. (a) Preformation Concepts : Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. 10 Hrs

(b) Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation 10 Hrs

2. Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. 10 Hrs

3. cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. 10 Hrs

4. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. 10 Hrs

5. Study of consolidation parameters : Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors– f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, studentsT-test, ANOVA test. 10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms : Tablets Vol.1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms : Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms : Parenteral medications Vol.1 2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol.1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

11. Quality Assurance Guide ; By Organization of Pharmaceutical producers of India.

12. Drug formulation manual; By D.P.S. Kohliand D.H. Shah. Eastern publishers, New Delhi.

13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.

14. Pharmaceutical Process Validation; By Fra. R .Berry and Robert A. Nash.

15. Pharmaceutical Preformulations; By J.J.Wells.

16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

17. Encyclopaedia of Pharmaceutical technology, Vol I–I

REGULATORY AFFAIRS

(R20_MPT1064T)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

Objectives

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs

1. (a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in- vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in–vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs

(b) Regulatory requirement for product approval : API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs 12 Hrs

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – 12 Hrs

Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

3. Non clinical drug development : Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). 12 Hrs

4.Clinical trials : Developing clinical trial protocols. Institutional review board/independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. 12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Inform a Health care Publishers.
3. New Drug Approval Process : Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guide book for drug regulatory submissions/SandyWeinberg By JohnWiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research : A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS – I

(R20_MPT1965P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Toper form In-vitro dissolution profile of CR/SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS-hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and Peppas plot and determine similarity factors.

SYLLABUS

Semester II

PHARMACEUTICS

2ND SEMESTER

MOLECULAR PHARMACEUTICS

(NANO TECHNOLOGY & TARGETED DDS)

(R20_MPT2061T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems

THEORY 60 Hrs

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12 Hrs

2. (a) TargetingMethods : Introduction preparation and evaluation**.**
(b) Nano Particles & Liposomes : Types, preparation and evaluation. 12 Hrs

3. Micro Capsules / Micro Spheres : Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 12 Hrs

4. Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 Hrs

5. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non viral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 Hrs

REFERENCES

1. YW. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyasand R.K. Khar, Controlled Drug Delivery-concepts and advances, Ballabh Prakashan, New Delhi, First edition 2002.
3. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (R20_MPT2062T)

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY 60 Hrs

1. (a) Drug Absorption from the Gastro intestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. 12 Hrs

(b) Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate.

(c) Gastro intestinal absorption : role of the dosage form : Solution (elixir, syrup and solution) as a dosage form , Suspension as a dosage form, Capsule as

a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.

(d) Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intra cellular pH Environment, Tight-Junction Complex.

2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. 12 Hrs

3. Pharmacokinetics : Basic considerations, pharmacokinetic models, 12 Hrs

(a) Compartment modeling : one compartment model- IV bolus, IV infusion, extra-vascular.

(b) Multi compartment model : two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax.

(c) Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: 12 Hrs

(a) Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence

studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods.

(b) Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (bio similar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

5. Application of Pharmacokinetics : Modified – Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies. 12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition, Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A.Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982

6. Current Concepts in Pharmaceutical Sciences : Biopharmaceutics, Swarbrick.J, Lea and Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowl and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.

10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.

11. Encyclopedia of Pharmaceutical Technology,Vol13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

12. Basic Pharmacokinetics, 1stedition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.

13. Absorption and Drug Development-Solubility, Permeability and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2

COMPUTER AIDED DRUG DEVELOPMENT

(R20_MPT2063T)

SCOPE

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY 60 Hrs

1. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Non linearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling 12 Hrs

b. Quality-by-Design In Pharmaceutical Development:

Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD – examples of application.

2. Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. 12 Hrs

3. (a) Computer aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. 12 Hrs

(b) Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

4. (a) Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations 12 Hrs

(b) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

(c) Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and FutureDirections. 12 Hrs

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006 , John Wiley & Sons.

2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing

3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

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COSMETICS AND COSMECEUTICALS

(R20_MPT2064T)

SCOPE

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives

- Upon completion of the course, the students shall be able to understand
- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY 60 Hrs

1.Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. 12 Hrs

2. Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eyelids, lips, hands, feet, nail, scalp, neck, body and under-arm. 12 Hrs

3. Formulation Building blocks: Building blocks for different product formulations of cosmetics/ cosmeceuticals. Surfactants – Classification and 12 Hrs

application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits.

Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes ; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12 Hrs

5. Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.

2. Poucher's perfume cosmetics and Soaps, 10th edition.

3. Cosmetics-Formulation, Manufacture and quality control, PP. Sharma, 4th edition

4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition

5. Cosmetic and Toiletries recent suppliers catalogue.

6. CTFA directory

PHARMACEUTICS PRACTICALS – II

(R20_MPT2965P)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation

2. Preparation and evaluation of Alginate beads

3. Formulation and evaluation of gelatine / albumin microspheres

4. Formulation and evaluation of liposomes / niosomes

5. Formulation and evaluation of spherules

6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.

7. Comparison of dissolution of two different marketed products / brands

8. Protein binding studies of a highly protein bound drug & poorly protein bounddrug

9. Bioavailability studies of Paracetamol in animals.

10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software

11. In vitro cell studies for permeability and metabolism

12. DoE Using Design Expert® Software

13. Formulation data analysis Using Design Expert® Software

14. Quality-by-Design in Pharmaceutical Development

15. Computer Simulations in Pharmacokinetics and Pharmacodynamics

16. Computational Modeling Of Drug Disposition

17. To develop Clinical Data Collection manual

18. To carry out Sensitivity Analysis, and Population Modeling.

19. Development and evaluation of Creams

20. Development and evaluation of Shampoo and Tooth paste base

21. To incorporate herbal and chemical actives to develop products

22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

SYLLABUS

Semester III

PHARMACEUTICS

3RD SEMESTER

RESEARCH METHODOLOGY& BIOSTATISTICS

(R20_MPT384T)

UNIT–I

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

UNIT–II

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

UNIT–III

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

UNIT–IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal

hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT–V

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