Department of Pharmaceutical Science and Technology

Maulana Abul Kalam Azad University of Technology,

West Bengal

(Formerly West Bengal University of Technology)

Haringhata-741249,Nadia,West Bengal,India.

Visions

To become a center of excellence and a leading global institutional unit in the field of pharmaceutical education and research by imparting transformative and cognitive education that creates new knowledge and produces environment conscious, highly knowledge-based pharma-professionals, educators and inventors, mastering skills to serve the challenges of pharmaceutical industries, research and health care system in our country, in particular, and worldwide as a whole.

Missions

- To develop an atmosphere to support, encourage and nurture students by providing high-quality education for acquiring knowledge and mastering skills to build them to their fullest potential to become future leaders of pharma-professionals, educators, and inventors.
- To develop students with a strong foundation of knowledge of Pharmaceutical sciences and technologies by additionally imparting cognizance in basic, clinical, and translational sciences with updated technologies
- Fostering a solid collaboration with Pharmaceutical Industry, National and International Institutes of repute and Experienced Industry Veterans
- To equip the students with the skills and mindset to thrive and burgeon globally
- To nurture students to think about the national and global needs related to the pharmaceutical field and to find the solution by rigorous research
- To continuously upgrade facilities, infrastructure, and instrumentations to keep students constantly updated with the current global knowledge.

Program Educational Objectives (PEOs)

1. To furnish extensive and advanced knowledge of pharmaceutical education to conduct quality pharmaceutical research.
2. To develop well educated pharmacy students for effective and sincere contribution to the health care system in the society.
3. To implant the urge for entrepreneurship and leadership quality in the future professional field.

Program Outcomes (POs)

Program Outcome	
PO1	**Pharmacy Knowledge**-Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioural, social, and administrative pharmacy sciences; and manufacturing practices.
PO2	**Planning Abilities-** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implementplans and organize work to meet deadlines.
PO3	**Problem analysis**- Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
PO4	**Modern tool usage** - Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
PO5	**Leadership skills**- Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.
PO6	**Professional Identity** - Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO7	**Pharmaceutical Ethics**- Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the

	outcomes associated with the decisions.
PO8	**Communication**-Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
PO9	**The Pharmacist and society** - Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
PO10	**Environment and sustainability** -Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
PO11	**Life-long learning**- Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Selfassess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

Program Specific Outcomes (PSOs)

PSO1:
Acquire the basic knowledge and concepts of Pharmaceutical Science and Technology.
PSO2:
Apply and expand the knowledge of all subjects in the research and development of pharmaceutical formulations.
PSO3:
Apply the knowledge of Pharmaceutical Science in predicting the drug information, disease information, formulation development, safety and efficacy of medicines.

PHARMACEUTICS

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPT 1061	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPT 1062	Drug Delivery System	4	4	4	100
MPT 1063	Modern Pharmaceutics	4	4	4	100
MPT 1064	Regulatory Affair	4	4	4	100
MPT 1965	Pharmaceutics PracticalI	12	6	12	200
MPT-1986	Seminar/Assignment	7	4	7	100
TOTAL		**35**	**26**	**35**	**700**
Semester II					
MPT 2061	Molecular Pharmaceutics (NanoTech and Targeted DDS)	4	4	4	100
MPT 2062	Advanced Biopharmaceutics &Pharmacokinetics	4	4	4	100
MPT 2063	Computer Aided Drug Delivery System	4	4	4	100
MPT 2064	Cosmetic and Cosmeceuticals	4	4	4	100
MPT 2965	Pharmaceutics Practical II	12	6	12	200
MPT-2986	Seminar/Assignment	7	4	7	100
	TOTAL	**35**	**26**	**35**	**700**

M PHARM –III[rd] Semester

Sr. No.	Course Code	Course	Contact Hours			Credit Points
			L	Project	Full Marks	
3	MPT-391	Discussion /Presentation(Proposal		2	100	2
4	MPT-392	Research Work		28	100	14
	SESSIONAL *					
1.	MPT-384	Research Methodology and Biostatistics*	4		100	4
2	MPT-381	Journal club		1	100	1
	Total		4	31		21

M.Pharm.IVSemester

Sr. No.	Course Code	Course	Contact Hours			Credit Points
			L		FullMarks	
1	MPT-491	Discussion/FinalPresentation		3	100	3
2	MPT-492	ResearchWork		31	100	16
	SESSIONAL					
3	MPT-481	Journal club		1	100	1
4	MPT-482	Participation in National Level Seminar/Conference/Workshop /Symposium/Training Programs(related to the specialization of the student). Participation in International Level Seminar/Conference/Workshop/ Symposium/Training Programs(related to the specialization of the student). Academic Award/research Award from State Level/National Agencies. Academic Award/research Award from International Agencies. Research/Review Publication in National Journals (Indexed in Scopus/Web of Science). Research/review Publication in International Journals (Indexed in Scopus/Web of Science).				3
	Total			35		23

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Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible/Activity
ParticipationinNationalLevelSeminar/Conference/Workshop/ Symposium/TrainingPrograms(relatedtothespecializationof The student)	01
ParticipationininternationalLevelSeminar/Conference/Works hop/Symposium/TrainingPrograms(relatedtothespecializatio nofthestudent)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research/ReviewPublicationinNationalJournals(IndexedinScopus /WebofScience)	01
Research/ReviewPublicationinInternationalJournals(Indexed inScopus/WebofScience)	02

Note: International Conference: Held Outside India

SEMESTER- I st

COURSE NAME: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
COURSE CODE: MPT-1061

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To know the various chemicals and reagents used in the analytical process.
CO2	To describe theoretical knowledge of various instruments
CO3	To apply the knowledge of instrumentation with skill and efficacy
CO4	To analyze the various single dosage form with various instruments
CO5	To evaluate the composition of combined dosage forms using different analytical techniques
CO6	To design a project for research and analysis

Course Contents: TOTAL HOURS: 60

1.a**. UV-Visiblespectroscopy:**Introduction,Theory,Laws,InstrumentationassociatedwithUV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

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

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. 11Hrs

2 **NMRspectroscopy:**QuantumnumbersandtheirroleinNMR,Principle,Instrumentation,Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemicalshift,Factorsinfluencingchemicalshift,Spin-Spincoupling,Couplingconstant,Nuclearmagnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 11Hrs

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 11Hrs

4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a)Paper chromatography b)Thin Layer chromatography c) Ion exchange chromatography
d)Column chromatography e) Gas chromatography f)High Performance Liquid chromatography

g)Affinity chromatography 11Hrs

5 a**. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 11Hrs
a)Paper electrophoresis b)Gel electrophoresis c)Capillary electrophoresis d)Zone electrophoresis e)Moving boundary electrophoresis f)Isoelectric focusing
b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg,, slaw, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.

6 **Immunological assays:** RIA(Radioimmunoassay), ELISA,Bioluminescenceassays.5Hrs

Learning Resources:

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, TimothyA. Nieman, 5thedition, Easternpress,Bangalore,1998.
3. Instrumental methods of analysis– Willards, 7thedition, CBS publishers.
4. Practical Pharmaceutical Chemistry– Beckettand Stenlake, VolII, 4thedition, CBSPublishers,NewDelhi,1997.
5. Organic Spectroscopy-William Kemp, 3rdedition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation- PDSethi,3rdEdition, CBS Publishers, New Delhi, 1997.
1. Pharmaceutical Analysis- Modern methods–Part B-W Munson,Volume11,Marcel Dekker Series

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COURSE NAME: DRUG DELIVERY SYSTEM
COURSE CODE: MPT-1062

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To study thedrug delivery system which helps in building a detailed concept of safe and effective transportation the specific active pharmaceutical ingredient to the target site of the body to achieve its desired therapeutic effect.
CO2	To understand the different approaches of development of technologies, transport system to design effective drug delivery in the human body.
CO3	To achieve detailed concept on various drug carriers, useful for safe, effective and target specific drug delivery system.
CO4	To acquire knowledge about latest drug delivery trends and will learn the theoretical basics to develop new formulation based on the personalized medication.
CO5	To expand the knowledge of recent advancements in parenteral delivery of protein and peptide and the approaches to design the drug delivery systems.
CO6	To explain the detailed concept of various vaccine delivery and different applications for clinical use.

COURSE CONTENT: TOTAL HOURS: 60

1.**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. Polymers: introduction, definition, classification, properties and application **Dosage Forms forPersonalizedMedicine:**Introduction,Definition,Pharmacogenetics,CategoriesofPatientsforPersonalizedMedicines:Customizeddrugdeliverysystems,BioelectronicMedicines,3Dprintingofpharmaceuticals,Telepharmacy. 10Hrs

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. 10Hrs

3 **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. 10Hrs

4 **Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers. 06

Hrs

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

6 **Protein and Peptide Delivery:** Barriers for protein delivery.FormulationandEvaluationofdeliverysystemsofproteinsandothermacromolecules. 08Hrs

7 **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 06Hrs

Learning Resources:

1. YW. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson,J.R.,LeeV.H.L,ControlledDrugDeliverySystems,MarcelDekker,Inc.,NewYork,1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published byWileyIntersciencePublication,JohnWileyandSons,Inc,NewYork,Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997(reprintin2001).
5. S.P.VyasandR.K.Khar,ControlledDrugDelivery-conceptsandadvances,VallabhPrakashan,NewDelhi,Firstedition2002

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

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COURSE NAME: MODERN PHARMACEUTICS
COURSE CODE: MPT-1063

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To develop the idea of various pre-formulation concepts which basically helps in understanding the physicochemical properties of a new drug candidate that could affect the drug performance and the development of a dosage form.
CO2	To describe about new dosage forms by applying the principles of optimization technique by implementation of systemic approaches to search for the best combination of product and/or processes characteristics under a given set of conditions composition or experimental conditions.
CO3	To design validation protocol for solid and liquid dosage forms.
CO4	To apply the Current Good Manufacturing Practices and Industrial management principles in dosage form development to understand the concept of good total quality management of pharmaceutical production unit.
CO5	To describe the insight of the process of compaction and compression in solid dosage form development.
CO6	To develop an in-depth conceptual clarity of consolidation parameters.

COURSE CONTENT: TOTAL HOURS: 60

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 Hr

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 Hr

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 Hr

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 Hr

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

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, students T-test , ANOVA test. 10 Hr

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. Kohli and 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 – III.

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COURSE NAME: REGULATORY AFFAIR
COURSE CODE: MPT-1064

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To acquire concepts of innovator and generic drugs, the process of drug development.
CO2	To explain regulatory guidance's and guidelines for filing and approval process of Investigational new drug (IND), New Drug Application (NDA), Abbreviated new drug application (ANDA).
CO3	To Prepare Dossiers which contains the collection of detailed documents containing information about a particular drug for submission to Regulatory Authority to get the grant of Regulatory Approval in any country.
CO4	To describe Post approval regulatory requirements for actives and drug products.
CO5	To explain the submission procedure of global documents in CTD/ eCTD formats.
CO6	To describe the clinical trials requirements for approvals for conducting clinical trials and Pharmacovigilance and monitoringprocess in clinical trial.

COURSE CONTENT: TOTAL HOURS: 60

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 - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. 12 Hrs

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 IsaderKaufer,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, Informa 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. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & 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

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COURSE NAME: PHARMACEUTICS PRACTICAL-1
COURSE CODE: MPT-1965

CO	**Description: After the completion of the course student will be able - -**
CO1	To evaluate therapeutic agents by various instrumental analytical techniques
CO2	To perform preformulation studies for development of various dosage forms
CO3	To design and optimize various types of controlled oral, transdermal and mucosal drug delivery systems
CO4	To evaluate various developed drug delivery systems using suitable methods.
CO5	To predict pharmaceutical factors affecting drug release kinetics

COURSE CONTENT:

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. To perform 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 Mucoadhesive tablets.
12. Formulation and evaluation of transdermal 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.

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COURSE NAME: SEMINAR/ ASSIGNMENTS
COURSE CODE: MPT-1986

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To develop knowledge on the recent developments in the field of Pharmaceutical Science and Technology
CO2	To understand the necessity of various fields in drug discovery process
CO3	To analyze the advancements of various techniques, methods, research in the field of Pharmaceutical Science and Technology
CO4	To apply the knowledge of the advancements in research
CO5	To employ the recent developments in projects
CO6	Have the ability to outline the projects for the society development

COURSE CONTENT:

Assignments and seminar based of recent developments, various techniques, methods in the field of pharmacology required for research and development.

SEMESTER- IIND

COURSE NAME: MOLECULAR PHARMACEUTICS (NANO TECH AND TARGETEDDDS)
COURSE CODE: MPT-2081

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To explain the different approaches for the development of novel drug delivery systems.
CO2	To describe the importance of site specific and target specific drug delivery system.
CO3	To be able to choose and use suitable polymers/excipients for safe, effective, target specific formulation design.
CO4	To gain theoretical knowledge of design and development of different delivery systems for a specific target of the drug.

CO5	To understand the basis of performing evaluation of the developed targeted drug delivery system.
CO6	To analyse and recommend the specific formulation approaches for site specific drug delivery.

COURSE CONTENT: TOTAL HOURS: 60

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

2 Targeting Methods: introduction preparation and evaluation. 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.

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 nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and 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, NewDelhi, First edition 1997 (reprint in 2001).

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COURSE NAME: ADVANCEDBIOPHARMACEUTICS &PHARMACOKINETICS
COURSE CODE: MPT-2062

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To develop the concept of different pharmacokinetic parameters and factors affecting Administration, Distribution, Metabolism and Excretion processes.
CO2	To understand in-depth knowledge of bioavailability and bioequivalence studies and their quantitative measurements.
CO3	To demonstrate the science behind comparing and analysing the *in vitro* drug release profiles for different marketed products.
CO4	To describe the different pharmacokinetic and pharmacodynamic parameters affecting bioavailability and drug effect.
CO5	To grab the theoretical basis of the applications of biopharmaceutics and pharmacokinetics in the development of different types of biopharmaceuticals and pharmaceuticals products.
CO6	To solve the potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

COURSE CONTENT: TOTAL HOURS: 60

1. Drug Absorption from the Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal 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 invivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12 Hrs

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, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. 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. 12 Hrs

4 Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: 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. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12 Hrs

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, 4th edition,Philadelphia, Lea and Febiger, 1991

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

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, 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, Leaand Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland 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, 4th edition, revised andexpande 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, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

12. Basic Pharmacokinetics,1 st edition,Sunil S Jambhekar and Philip J Breen, pharmaceuticalpress, RPS Publishing,2009.

13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

Department of Pharmaceutical Science and Technology
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COURSE NAME: COMPUTER AIDED DRUGDELIVERY SYSTEM
COURSE CODE: MPT-2063

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To explain the History of Computers in Pharmaceutical Research and Development and Computational Modelling of Drug Disposition.
CO2	To describe the use of computers in preclinical and clinical development.
CO3	To optimize pharmaceutical formulation development techniques.
CO4	To demonstrate the use of computers in market analysis.
CO5	To explain the utility of Artificial Intelligence (AI) and Robotics in pharmaceuticals.
CO6	To gain in-depth knowledge in Computational fluid dynamics (CFD).

COURSE CONTENT: TOTAL HOURS: 60

1. a. 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, Nonlinearity 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. 12 Hrs

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 Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal

Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis 12 Hrs4

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

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 12 Hrs

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

Current Challenges and Future Directions. 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.

COURSE NAME: COSMETIC ANDCOSMECEUTICALS
COURSE CODE: MPT-2064

CO	Description: After the completion of the course the students will be able- - -
CO1	To understand the manufacturing of cosmeceuticals.
CO2	To design the quality and regulatory provisions for cosmeceuticals in India and for export of the same
CO3	To explain the biological aspects as well as the side effects related to cosmeceuticals.
CO4	To demonstrate the theory of building blocks of cosmetics, use of different preservatives, their merits, demerits.
CO5	To design the method of development of different cosmeceutical products.
CO6	To compile the applications of different herbal cosmetics, their uses, challenges in manufacturing and development.

COURSE CONTENT: TOTAL HOURS: 60

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 manufactureof cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

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, eye lids, 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 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. 12 Hrs

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‟sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4thedition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

COURSE NAME: PHARMACEUTICS PRACTICAL-II
COURSE CODE: MPT-2985

CO	**Description: After the completion of the course student will be able - -**
CO1	To compare the dissolution efficiency of various marketed pharmaceutical products
CO2	To formulate and evaluate various cosmetic products
CO3	To design experiments based on QbD for optimization of drug delivery
CO4	To analyze and predict pharmacokinetic parameters using softwares
CO5	To evaluate computational modeling of drug disposition

COURSE CONTENT:

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 gelatin /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 bound drug
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 Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

COURSE NAME: SEMINAR/ ASSIGNMENTS
COURSE CODE: MPT-2986

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To understand the knowledge of Pharmaceutical Science and Technology
CO2	To discover the recent developments in the field of Pharmaceutical Science and Technology
CO3	To apply the theoretical knowledge in research/project.
CO4	To increase the ability to analyze the results of research and /project
CO5	To gain the competence in designing projects
CO6	To evaluate the necessity of the recent developments in the field of Pharmaceutical Science and Technology

COURSE CONTENT:
Assignments and seminar based of recent developments, various techniques, methods in the field of pharmacology required for research and development.

SEMESTER- IIIrd

COURSE NAME: DISCUSSION/ PRESENTATION
COURSE CODE: MPT-391

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To identify the knowledge of Pharmaceutical science and technology
CO2	To gain idea about the modern areas in Pharmaceutical science and technology
CO3	To apply the knowledge of Pharmaceutical science and technology in research
CO4	To find new techniques and knowledge in Pharmaceutical science and technology
CO5	To expand the knowledge of the newer developments of Pharmaceutical science and technology
CO6	To evaluate the value of subject in pharmaceutical science and research

COURSE NAME: RESEARCH WORK
COURSE CODE: MPT-392

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To understand the knowledge of Pharmaceutical science and technology
CO2	Ability to describe the various concepts, methods of Pharmaceutical science and technology
CO3	To relate the knowledge of Pharmaceutical science and technology in research
CO4	To modify the knowledge of Pharmaceutical science and technology in projects and research
CO5	To outline new projects with the wide knowledge of the subjects
CO6	To ability to assess the various problems related with the research

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COURSE NAME: RESEARCH METHODOLOGY AND BIOSTATISTICS
COURSE CODE: MPT-384

CO	Description: After the completion of the course the students will be able- - -
CO1	To understand the guidelines and requirements for preclinical research
CO2	To apply the knowledge of biostatistics analyzing various data
CO3	To design a project following the different components of research
CO4	To interpret the guidelines and requirements for clinical research
CO5	To employ the concept of good clinical practice and good laboratory practice in research
CO6	To apply the knowledge of guidelines in clinical research and preclinical studies

COURSE CONTENT:

1. General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls,randomization,crossoverdesign,placebo,blindingtechniques.

2. **Biostatistics:** Definition, application, sample size, importance of sample size, factors influencingsamplesize,dropouts,statisticaltestsofsignificance,typeofsignificancetests,parametrictests(students"t"test,ANOVA,Correlationcoefficient,regression),non-parametrictests(wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

3. **Medical Research:** History,valuesinmedicalethics,autonomy,beneficence,non-maleficence,doubleeffect,conflictsbetweenautonomyandbeneficence/non-maleficence,euthanasia,informedconsent,confidentiality,criticismsoforthodoxmedical ethics,importanceofcommunication, 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.

4. **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, recordkeeping, SOPs, personnel and training, transport of lab animals.

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

Learning Resources:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

2. EthicalGuidelinesforBiomedicalResearchonHumanSubjects2000.IndianCouncilofMedicalResearch, NewDelhi.
3. cpcsea.nic.in
4. Declaration of Helsinki-WMA-The World Medical Association. https://www.wma.net › what-we-do › medical-ethics
5.Research Methodology: Methods and Techniques by C R Kothari.

SEMESTER- IVth

COURSE NAME: DISCUSSION/ PRESENTATION
COURSE CODE: MPT-491

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To analyze a problem in the area of pharmaceutical science and technology
CO2	To outline the project for a novel research to solve a problem
CO3	To apply the concepts of the pharmaceutical science and technology in framing a project
CO4	To apply the practical knowledge of the pharmaceutical science and technology in framing a project
CO5	To assess various parameters of the research work
CO6	To make conclusions of the work and its implication in the society

COURSE NAME: RESEARCH WORK
COURSE CODE: MPT-492

CO	**Description: After the completion of the course the students will be able- - -**
CO1	To identify the problem in the area of pharmaceutical science and technology
CO2	To frame a novel research to solve a problem
CO3	To employ the knowledge of the pharmaceutical science and technology in framing a project
CO4	To apply the practical knowledge of the pharmaceutical science and technology according to international standards and guidelines
CO5	To assess and apply the biostatistics and other concepts in evaluation of data
CO6	To conclude the findings of the research and its implication in the society