M. Pharmacy Hand Book
2020-21

K L COLLEGE OF PHARMACY

Koneru Lakshmaiah Education Foundation
(Category -1, Deemed to be University estd. u/s. 3 of the UGC Act, 1956)
Accredited by NAAC as 'A++' ❖Approved by AICTE ❖ ISO 9001-2015 Certified
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KL University Vision

To be a globally renowned university.

K L University Mission:

To impart quality higher education and to undertake research and extension with emphasis on application and innovation that cater to the emerging societal needs through all-round development of students of all sections enabling them to be globally competitive and socially responsible citizens with intrinsic values.

M1 - To impart quality higher education

M2 - To undertake research and extension with emphasis on application and innovation
M3- Cater to the emerging societal needs through all round development of students of all sections.

M4 - To be globally competitive and socially responsible citizens with intrinsic values.

KL University Academic Goals

1. To offer academic flexibility by means of Choice based credit systems and the like
2. To identify and introduce new specializations that offer programs in emerging areas there in.
3. Toincorporateintothecurriculumtheapplicationorientationandusehighstandardsofcompetencefo racademicdelivery.
4. To design and implement educational system adhering to outcome based international models
5. To introduce and implement innovation in teaching and learning process to strengthen academic delivery
6. To offer academic programs at UG, PG, Doctoral, Post-Doctoral which are industry focused and incorporates trans-discipline, inter- discipline aspects of the education system.
7. To deliver higher education that includes technologies and meeting the global requirements

Vision and Mission of the Department

Vision: Lead the future of global healthcare and well-being of the communities we serve.

Mission: To produce quality Pharmacy professionals having strong theoretical foundation, innovative ideas, good design experience by bridging industry-academic gap in Pharma Sector through the use of technology and innovative teaching and exposure to research and progress with social ethics.

Mission Statements

M1. Education: Provide the most comprehensive and highest quality education for pharmaceutical sciences in a learning environment that embraces diversity, equity, integrity, ethics, moral courage and accountability.

M2. Community service: Conduct health education programs to the community to prevent disease and improve public health and well-ness by fostering an environment that promotes the safe, efficacious, and cost-effective use of medications.

M3. Research: Develop a passion for discovery and innovations with multidisciplinary collaborative research and engage in creative partnerships locally and globally to advance health education, research, and practice.

M4. Entrepreneurship: Encourage and support resourcefulness, originality, imagination, ingenuity, and vision in our students, faculty, and staff. Foster the development of entrepreneurs who have the ability to dream, inspire and innovate and courage to envisage the commercial success and socio economic productivity of innovations.

Programme Educational Objectives (PEO's) - M.Pharm Pharmaceutics

PEO1	**Knowledge & Understanding:** The pharmacy students should possess upon graduation, knowledge of pharmaceuticals, medication use and their safety and effectiveness.
PEO2	**Skill:** The graduate should be able to demonstrate his skills in providing quality pharmaceuticals, drug information and therapy including legal and ethical aspects.
PEO3	**Attitude:** The graduate should be able to inculcate the current knowledge, changes in technology, continuous upgrading of professional information and participation in implementation of National health programmes.

Programme Outcomes (PO's) - M.Pharm Pharmaceutics

PO1	**Pharmaceutical Knowledge:** Apply the knowledge of science, technology, and pharmaceutical specialization to cater the needs of pharmaceutical industry, biotechnology industry, health care industry and other related fields.
PO2	**Design/Development of solutions:** Identify the complex public health and societal problems, drug/product related problems, there after conduct investigations, design experiment, analyse & interpret the data to design/develop the solutions for combating those problems.
PO3	**Individual and Team-work:** Communicate and work effectively as an individual as well as in diverse teams of multidisciplinary settings while performing duties or handling projects.
PO4	**Environment and sustainability**: Understand the impact of the professional pharmaceutical solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
PO5	**Ethics**: Apply ethical principles and commit to professional ethics and responsibilities and norms of the pharmacy practice.
PO6	**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.

Program Specific Outcomes (PSO's) - M.Pharm Pharmaceutics

PSO1	To impart knowledge and skills on criteria for formulation design, product development, in vitro & biopharmaceutical evaluation, and optimization for better therapeutic efficacy.
PSO2	To undertake research projects and drive towards entrepreneurship to cater the needs of society with respect to health care sector.

Mapping of PEOs with Mission statement

S.No	Description of PEOs	Key Components of Mission			
		M 1	**M 2**	**M 3**	**M 4**
		High quality Education	Community service	Research and Development	Enterpreneurship
PEO 1	**Knowledge & Understanding:** The pharmacy students should possess upon graduation, knowledge of pharmaceuticals, medication use and their safety and effectiveness.	✓	✓		
PEO 2	**Skill:** The graduate should be able to demonstrate his skills in providing quality pharmaceuticals, drug information and therapy including legal and ethical aspects.	✓			✓
PEO 3	**Attitude:** The graduate should be able to inculcate the current knowledge, changes in technology, continuous upgrading of professional information and participation in implementation of National health programmes.			✓	

Program Articulation Matrix (Mapping of Courses with POs)

S.No.	Course Code	CourseName	Category	L	T	P	S	Cr	POS						PSOs	
									1	2	3	4	5	6	1	2
1	20PY5101	Modern Pharmaceutical Analytical Techniques	PCC	4	0	0	0	4	3	2						
2	20PY5102	Drug Delivery System	PCC	4	0	0	0	4		3					3	
3	20PY5103	Modern Pharmaceutics	PCC	4	0	0	0	4	2	2						
4	20PY5104	Regulatory Affair	PCC	4	0	0	0	4					2	3		
5	20PY5105	Pharmaceutics Practical I	PCC	0	0	12	0	6			3				3	2
6	20PY5106	Seminar/Assignment	skill	0	0	8	0	4						2		
7	20PY5107	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	PCC	4	0	0	0	4		2	3					
8	20PY5108	Advanced Biopharmaceutics & Pharmacokinetics	PCC	4	0	0	0	4		3					2	
9	20PY5109	Computer Aided Drug Delivery System	PCC	4	0	0	0	4	3			3				
10	20PY5110	Cosmetic and Cosmeceuticals	PCC	4	0	0	0	4		2						
11	20PY5111	Pharmaceutics Practical II	PCC	0	0	12	0	6		3				3		
12	20PY5112	Seminar/Assignment	skill	0	0	8	0	4						2		
13	20PY5113	Research Methodology and Biostatistics	PCC	4	0	0	0	4				2	3			
14	20PY5114	Journal club	skill	0	0	2	0	1					2	2		
15	20PY5115	Discussion / Presentation (Proposal Presentation)	skill	0	0	4	0	2		2						
16	20PY5116	Research Work	skill	0	0	28	0	14		2	2					3
17	20PY5117	Journal Club	skill	0	0	2	0	1					2	2		
18	20PY5118	Research Work	skill	0	0	33	0	16		2	2					3
19	20PY5119	Discussion/Final Presentation	skill	0	0	6	0	3		2						3
20	20PY5120	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	skill	0	0	8	0	4			2			2		
Total				72	0	197	0	97								

Academic 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. 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.

Graduate Requirements

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.

Credit assignment

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.

8.2. 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 creditsare distributed semester-wise as shown in Table. 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.

Semester wise credits distribution Semester Credit Points

Semester	**Credit Points**
I	26
II	26
III	21
IV	24
Total credit points for the program	**97**

Course Category wise Credit Distribution

S No	Course Category	Short name	No of Courses	Total credits
1	Professional Courses	PC	11	48
2	Skill	Skill	9	49

Course Category wise Credit Distribution

PC

S No	Course Code	Course Title	L	T	P	S	CR	CH
1	20PY5101	Modern Pharmaceutical Analytical Techniques	4	0	0	0	4	4
2	20PY5102	Drug Delivery Systems	4	0	0	0	4	4
3	20PY5103	Modern Pharmaceutics	4	0	0	0	4	4
4	20PY5104	Regulatory Affairs	4	0	0	0	4	4
5	20PY5105	Pharmaceutics Practical I	0	0	12	0	6	12
6	20PY5107	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	0	0	0	4	4
7	20PY5108	Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	0	4	4
8	20PY5109	Computer Aided Drug Delivery System	4	0	0	0	4	4
9	20PY5110	Cosmetic and Cosmeceuticals	4	0	0	0	4	4
10	20PY5111	Pharmaceutics Practical II	0	0	12	0	6	12
11	20PY5113	Research Methodology and Biostatistics	4	0	0	0	4	4

SKILL

S No	Course Code	Course Title	L	T	P	S	CR	CH
1	20PY5106	Seminar/Assignment	0	0	8	0	4	8
2	20PY5112	Seminar/Assignment	0	0	8	0	4	8
3	20PY5114	Journal club	0	0	2	0	1	2
4	20PY5115	Discussion / Presentation (Proposal Presentation)	0	0	4	0	2	4
5	20PY5116	Research Work	0	0	28	0	14	28
6	20PY5117	Journal Club	0	0	2	0	1	2
7	20PY5118	Research Work	0	0	33	0	16	33
8	20PY5119	Discussion/Final Presentation	0	0	6	0	3	6
9	20PY5120	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	0	0	8	0	4	8

CBCS STRUCTURE

SNO	COURSE CODE	COURSE NAME	L	T	P	S	CREDITS	CH
1	20PY5101	Modern Pharmaceutical Analytical Techniques	4	0	0	0	4	4
2	20PY5102	Drug Delivery Systems	4	0	0	0	4	4
3	20PY5103	Modern Pharmaceutics	4	0	0	0	4	4
4	20PY5104	Regulatory Affairs	4	0	0	0	4	4
5	20PY5105	Pharmaceutics Practical I	0	0	12	0	6	12
6	20PY5106	Seminar/Assignment	0	0	8	0	4	8
1	20PY5107	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	0	0	0	4	4
2	20PY5108	Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	0	4	4
3	20PY5109	Computer Aided Drug Delivery System	4	0	0	0	4	4
10	20PY5110	Cosmetic and Cosmeceuticals	4	0	0	0	4	4
11	20PY5111	Pharmaceutics Practical II	0	0	12	0	6	12
12	20PY5112	Seminar/Assignment	0	0	8	0	4	8
13	20PY5113	Research Methodology and Biostatistics*	4	0	0	0	4	4
14	20PY5114	Journal club	0	0	2	0	1	2
15	20PY5115	Discussion / Presentation (Proposal Presentation)	0	0	4	0	2	4
16	20PY5116	Research Work	0	0	28	0	14	28
17	20PY5117	Journal Club	0	0	2	0	1	2
18	20PY5118	Research Work	0	0	33	0	16	33
19	20PY5119	Discussion/Final Presentation	0	0	6	0	3	6
20	20PY5120	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	0	0	8	0	4	8

Professional Courses

Course code: 20PY5101 Course name: Modern Pharmaceutical Analytical Techniques

L-T-P: 4-0-0 Credits: 4 Contact hours: 04

CO#	Course Outcome	PO/PSO	BTL
CO1	Discuss the fundamental principles and applications of UV-visible, IR, flame emission, atomic absorption spectroscopy and spectroflourimetry	1,2	2
CO2	Understand the principles and applications of NMR spectroscopy in determination of structure of typical organic chemical compounds	1,2	3
CO3	Appraise the role of MS spectrometry in elucidation of the structure of typical organic chemical compounds using	1,2	3
CO4	Document the principles and applications of chromatographic, and electrophoretic separation techniques	1,2	2
CO5	Describe the concepts in electrophoresis and radio-immuno assays	1,2	2
CO6	Describe the principles and applications of X-Ray crystallography	1,2	3

Syllabus

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

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

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

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

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

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.

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

Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing**.**

Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-ray diffraction.

Reference Books

8. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
9. Instrumental methods of analysis –Willards, 7th edition, CBS publishers.
10. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
11. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
12. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
13. Spectrophotometric identification of Organic Compounds- Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.

Test Books

1. Instrumental Methods of Chemical Analysis by B.K. Sharma- Krishna Prakashan Media (P) Ltd, 2014.
2. Organic spectroscopy by Y.R. Sharma- 5th edition, Chand, 2013.
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors- 3rd edition-Wiley, 2007.
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel-6th edition, Pearson Education, 2009.
5. Organic spectroscopy by William Kemp- 3rd edition, ELBS, 1991.
6. Instrumental Methods Of Chemical Analysis by G.R. Chatwal, Sham Anand-Himalay publishing House, 2011.

Course Code: 20PY5102 **Course Name:** Drug Delivery Systems

L-T-P-S: 4-0-0-0 **Credits: 4** **Contact Hours: 4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Understand the concepts involved in SR and CR drug delivery systems	2/1	2
CO2	Identify suitable drugs and polymers for specific controlled drug delivery systems and discuss modern strategies	2/1	2
CO3	Understand various approaches for rate controlled and ocular drug delivery systems	2/1	2
CO4	Understand the formulation concepts involved in development of GRDDS, buccal and transdermal DDS	2/1	2
CO5	Illustrate the evaluation of buccal and transdermal DDs	2/1	3
CO6	Illustrate the need and application of novel strategies in delivery of biosimilars like proteins, peptides and vaccines	2/1	3

Syllabus:

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

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.

Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

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.

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

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

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

Reference books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc.
2. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim

Text books:

1. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, VallabhPrakashan, New Delhi.
2. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers& Distributors, New Delhi.
3. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York.
4. D.M. Brahmankar, Sunil B. Jaiswal, Biopharmaceutics and pharmacokinetics, A Treatise, VallabhPrakashan, New Delhi

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

Course Code: 20PY5103 **Course Name: Modern Pharmaceutics**

L-T-P-S:4-0-0-0 **Credits:4** **Contact Hours:4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Discuss various preformulation concepts in dosage form development	**1**	**2**
CO2	Develop new dosage forms by applying the principles of optimization	**2**	**3**
CO3	Design validation protocol for solid and liquid dosage forms	**2**	**2**
CO4	Apply the cGMP and Industrial management principles in dosage form development	**2**	**3**
CO5	Understand the process of compaction and compression in solid dosage form development	**1**	**2**
CO6	Understand the study of consildation parameter	**1**	**2**

Syllabus:

Preformulation 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.

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.

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

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.

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

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.

Reference books:

1. Modern Pharmaceutics; By Gillbert and S. Banker.
2. Remington's Pharmaceutical Sciences.
3. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
4. Physical Pharmacy; By Alfred martin
5. Bentley's Textbook of Pharmaceutics – by Rawlins.
6. Good manufacturing practices for Pharmaceuticals: A plan for total qualitycontrol, Second edition; By Sidney H. Willig.
7. Quality Assurance Guide; By Organization of Pharmaceutical producers ofIndia.
8. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Easternpublishers, New Delhi.
9. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
10. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
11. Pharmaceutical Preformulations; By J.J. Wells.
12. Applied production and operations management; By Evans, Anderson,Sweeney and Williams.
13. Encyclopaedia of Pharmaceutical technology, Vol I – III

Text books:

1. Theory and Practice of Industrial Pharmacy ByLachmann 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 Lachman

Course Code:20PY5104 **Course Name: Regulatory Affairs**

L-T-P/S: 4-0-0-0 **Credits: 4** **Contact Hours: 4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Understand the concepts of innovator and generic drugs in drug development process	5	2
CO2	Understand Regulatory requirements for new drug application approval in pharmaceuticals	6	2
CO3	Understand ICH guidelines for filing and approval process of drug products in different countries	5	2
CO4	Analyse the post approval regulatory requirements for products and submission of global documents in Common Technical Document/ eCTD formats	6	3
CO5	Illustrate the regulatory procedures involved in non-clinical and clinical drug development	6	3
CO6	Apply the principles of regulatory affairs in drug development process, filing and approval, non-clinical and clinical drug development in global scenario	6	3

Syllabus:

Drug development concepts: Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , HatchWaxman 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.

Product approval requirements: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

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

Post product approval documents: CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison.

Clinical and non-clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

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.

REFERENCE BOOKS

- Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
- 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.

TEXT BOOKS

- Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
- FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
- New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
- Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

WEB SOURCES

- www.ich.org/
- www.fda.gov/
- europa.eu/index_en.html
- https://www.tga.gov.au/tga-basics

Course Code: 20PY5105 **Course Name: Pharmaceutics Practical I**

L-T-P-S: 0-0-12-0 **Credits:6** **ContactHours:12**

CO#	Course Outcome	PO/PSO	BTL
CO1	Analyse the Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer	3/2	4
CO2	Demonstrate the experiments using HPLC and Gas Chromatography	3/2	4
CO3	Estimate Pharmacopoeial substances by Fluorimetry andFlame Photometry	3/2	4
CO4	Formulate and evaluate the different marketed formulations	3/1	4
CO5	Analyze the precompression parameters and understand the influence of excipients on product performance	3/1	4
CO6	Construct the release kinetic plots through model dependent and independent methods	3/1	4

Syllabus:

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 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

Course Code: 20PY5107 **Course Name: Molecular Pharmaceutics (Nano Tech and Targeted DDS)**

L-T-P-S:4-0-0-0 **Credits:4** **Contact Hours:4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Understand the concepts involved in Drug targeting systems	2	2
CO2	Understand the preparation and evaluation of targeting methods	2	2
CO3	Design and develop various delivery systems for a specific drugtargets	2	2
CO4	Understand the preparation and evaluation of Intra nasal formulations	2	2
CO5	Understand the nucleic acid- based therapeutic drug delivery system	2	2
CO6	Applications of the Potential target diseases for gene therapy	2	3

Syllabus:

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

Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Noisome, Aquasomes, Phytosomes, Electrosomes.

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

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo genetherapy).

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.

Text books:

1.YW.Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., NewYork,

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

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi.

Journals

1. European Journal of Biopharmaceutics andPharmacokinetics
2. Indian Journal of Pharmaceutical Sciences(IPA)
3. Indian drugs(IDMA)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)desirable

Course Code: 20PY5108 **Course Name:** Advanced Biopharmaceutics and Pharmacokinetics

L-T-P-S: 4-0-0-0 **Credits: 4** **Contact Hours: 4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Understand the mechanisms and factors affecting ADME processes through GIT	2/1	2
CO2	Discuss several biopharmaceutic considerations, BCS, IVIVC and permeability in drug product design and in vitro drug product performance	2/1	2
CO3	Understand the impact of drug interactions on drug action	2/1	2
CO4	Explain the protocol for bioavailability/bioequivalence studies and their role in generic product development	2/1	2
CO5	Illustrate the assessment of pharmacokinetic parameters assuming different models	2/1	3
CO6	Illustrate the application of pharmacokinetic principles in development of drug products and biosimilars	2/1	3

Syllabus:

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 in vivo 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.

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. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.

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.

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.

Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

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.

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.

Reference books:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition, Philadelphia, Lea and Febiger, 1991.
2. Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995.
3. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, MackPublishing Company, Pennsylvania 1989.
4. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton,Illinois, 1971.
5. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,James. G.Boylan, Marcel Dekker Inc, New York, 1996.

6. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip JBreen, Pharmaceutical press, RPS Publishing, 2009.
7. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.

Text books:

1. Biopharmaceutics and Pharmacokinetics, A. Treatise, D. M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
2. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
3. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath, Prism Book.
4. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekker Inc., New York, 1982.
5. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
6. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel, 1987.

Journals

1. European Journal of Biopharmaceutics and Pharmacokinetics
2. Indian Journal of Pharmaceutical Sciences (IPA)
3. Indian drugs (IDMA)
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable.

Course Code: 20PY5109 **Course Name:** Computer Aided Drug Delivery Systems

L-T-P-S: 4-0-0-0 **Credits: 4** **Contact Hours: 4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Explain the history of computers in pharmaceutical research and development	1	2
CO2	Explain computational modeling of drug disposition	1,4	2
CO3	Apply the approaches of optimization techniques in pharmaceutical formulation	1,4	3
CO4	Understand the importance of computers in biopharmaceutical characterization	1,4	2
CO5	Understand the role of computer simulations in PK-PD and clinical data management	1,4	3
CO6	Illustrate the application of AI, robotics and CFD in pharmacy field	1,4	3

Syllabus:

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.

Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

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.

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.

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 vitroin vivo* correlation, Biowaiver considerations.

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

Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.

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

Reference books:

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

Text books:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing.

Course Code: 20PY5110 **Course Name: Cosmetics And Cosmeceuticals Systems**

L-T-P-S: 4-0-0-0 **Credits: 4** **Contact Hours: 4**

COURSE OUTCOMES (COs):

CO. No	Course Outcome (CO)	PO/PSO	BT
CO1	To know the Regulatory provisions related to the import, manufacture and sale of cosmetics.	2/1	2
CO2	Understand the diverse skin problems and how to overcome through skin preparations	2/1	2
CO3	To understand the formulation and evaluation of a variety of cosmetic products.	2/1	2
CO4	Understanding the key ingredients and basic science to develop cosmetics and Cosmeceuticals.	2/1	2
CO5	To gain the knowledge of the various technologies involved in cosmetics manufacture.	2/1	2
CO6	To understand the Design of cosmeceuticals and herbal formulations.	2/1	2

Syllabus:

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.

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.

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.

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.

Formulation Building blocks:

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.

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.

Text Books:

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,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. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
7. Cosmetics- Formulation, Manufacturing and Quality control –P.P. Sharma
8. Herbal Cosmetics Hand Book- H. Panda
9. Herbal Cosmetics by P. K Chattopadhyay
10. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda
11. Pharmaceutical Jurisprudence., Dr.G.KJani
12. Cosmetic Technology.,SanjuNanda,ArunNanda,RoopK.Khar
13. Cosmeceuticals .,Y Madhusudhan Rao
14. Law Relating to Drugs & Cosmetics.,Vijaya Malik.
15. Cosmetics science & Technology Second Edition Volume I
16. POUCHER"S Perfumes,Cosmetics and Soaps 10th Edition ,Hilda Butler

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

Web References

1. https://www.bis.gov.in
2. https://www.fda.gov/Cosmetics/default.htm

Course Code: 20PY5111 **Course Name: Pharmaceutics Practical II**

L-T-P-S: 0-0-12-0 **Credits: 6** **Contact Hours: 12**

CO#	Course Outcome	PO/PSO	BTL
CO1	Demonstrate the practical skills in development and evaluation of novel systems	3/1	4
CO2	Demonstrate the BA studies, PK-PD analysis, and IVIVC	3/1	4
CO3	Apply computational tools in product development and optimization	6/1	4
CO4	Understand the concept and application of PK-PD simulation models	6/1	3
CO5	Understand the clinical data collection and population modeling	6	2
CO6	Demonstrate the formulation and evaluation of cosmeceuticals	1	4

Syllabus:

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 Winnolin, 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 Code: 20PY5113 **Course Name: Research Methodology and Biostatistics**

L-T-P-S: 4-0-0-0 **Credits: 4** **Contact Hours: 4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Understand the basic principles of research methodology and its role in pharmaceutical aspect	4,5	2
CO2	Understand the basic concepts of biostatistics	4,5	2
CO3	Illustrate the importance of biostatistics in research	4,5	3
CO4	Develop research proposal following the principles of medical research	5	3
CO5	Understand and apply the guidelines of CPCSEA in preclinical experimentation	5	3
CO6	Understand the principles of Declaration of Helsinki	5	2

Syllabus:

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

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests

Testing of Hypothesis: 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.

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.

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.

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

Reference Books:

- Remington"s Pharmaceutical Sciences
- Theory & Practice of Industrial Pharmacy by Lachman
- Statistics for business and economics 3rd edition by Vikas books publications
- Biostatistics & Computer applications by GN Rao and NK Tiwari
- Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
- Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
- Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
- Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
- Fundamentals of Biostatistics by Khan and Khanum
- Research Methodology by RK Khanna bis and SuvasisSaha
- Research methods and Quantity methods by G.N.Rao

Text Books:

- Deepak Chawla NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
- Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd.)

SKILL COURSES

Course Code: 20PY5106 **Course Name:** Seminar/Assignment

L-T-P-S: 0-0-8-0 **Credits: 4** **Contact Hours: 8**

CO#	Course Outcome	PO/PSO	BTL
CO1	Select topic from the course content for deep learning towards seminar presentation	6	2
CO2	Develop advanced content and present it as seminar	6	2
CO3	Select topic from the course content for deep learning towards assignment preparation	6	2
CO4	Develop advanced content and present it as assignment	6	2

Course Code: 20PY5112 **Course Name:** Seminar/Assignment

L-T-P-S: 0-0-8-0 **Credits: 4** **Contact Hours: 8**

CO#	Course Outcome	PO/PSO	BTL
CO1	Select topic from the course content for deep learning towards seminar presentation	6	2
CO2	Develop advanced content and present it as seminar	6	2
CO3	Select topic from the course content for deep learning towards assignment preparation	6	2
CO4	Develop advanced content and present it as assignment	6	2

Course Code: 20PY5114 **Course Name:** Journal Club

L-T-P-S: 0-0-2-0 **Credits: 1** **Contact Hours: 2**

CO#	Course Outcome	PO/PSO	BTL
CO1	Select a research paper published in reputed journal by using search engines and databases	5,6	2
CO2	Critically appraise the published research work	5,6	2
CO3	Develop a report	5,6	2
CO4	Present the critical observations and discuss	5,6	2

Course Code: 20PY5115 **Course Name:** Discussion / Presentation (Proposal Presentation)

L-T-P-S: 0-0-4-0 **Credits: 2** **Contact Hours: 4**

CO#	Course Outcome	PO/PSO	BTL
CO1	Identify the research problem	2	2
CO2	Discuss research problem with team, peers and guide for solution	2	2
CO3	Develop a protocol report on the critically appraised research problem with aim and objectives	2	2
CO4	Analyse and present the critically appraised research problem in appropriate form and discuss the plan of work	2	4

Course Code: 20PY5116 **Course Name:** Research Work

L-T-P-S: 0-0-28-0 **Credits: 14** **Contact Hours: 28**

CO#	Course Outcome	PO/PSO	BTL
CO1	Conduct literature review and come to conclusions on selection of drugs/excipients/methods/techniques	2/2	2
CO2	Develop a research protocol or plan of work	2/2	2
CO3	Conduct research experiments to meet the aim and objectives of proposed research work	2,3/2	4
CO4	Evaluate the findings and plan alterations or new methodologies or procedures for further improvement	2,3/2	5
CO5	Document the findings of conducted experiments	2/2	2
CO6	Interpret the results obtained and plan further activities	2,2/2	4

Course Code: 20PY5117 **Course Name:** Journal Club

L-T-P-S: 0-0-2-0 **Credits: 1** **Contact Hours: 2**

CO#	Course Outcome	PO/PSO	BTL
CO1	Select a research paper published in reputed journal by using search engines and databases	5	2
CO2	Critically appraise the published research work	5,6	2
CO3	Develop a report	5,6	2
CO4	Present the critical observations and discuss	5,6	2

Course Code: 20PY5118 **Course Name:** Research Work

L-T-P-S: 0-0-33-0 **Credits: 16** **Contact Hours: 33**

CO#	Course Outcome	PO/PSO	BTL
CO1	Review the latest literature in selected area of work	2/2	2
CO2	Conduct research experiments to meet the aim and objectives of proposed research work	2,3/2	4
CO3	Evaluate the findings and plan alterations or new methodologies or procedures for further improvement	2,3/2	5
CO4	Document the findings of conducted experiments	2/2	2
CO5	Interpret the results obtained and summarize the work with a conclusion	2,3/2	4
CO6	Draft the chapters for thesis	2/2	2

Course Code: 20PY5119 **Course Name:** Discussion / Final Presentation

L-T-P-S: 0-0-6-0 **Credits: 3** **Contact Hours: 6**

CO#	Course Outcome	PO/PSO	BTL
CO1	Interpret the observations and results	2/2	2
CO2	Develop the presentation in an organized manner	2/2	2
CO3	Explain the followed methods and results	2/2	4
CO4	Defend the questions from experts and peers	2/2	4

Course Code: 20PY5120 **Course Name: Co-curricular Activities**

L-T-P-S: 0-0-8-0 **Credits: 4** **Contact Hours: 8**

CO#	Course Outcome	PO/PSO	BTL
CO1	Participate in external scientific/technical programs like conferences/seminars/symposia	3,6	3
CO2	Present their technical or research work	3,6	3
CO3	Perform scientific paper writing and critical thinking	3,6	3
CO4	Perform team management and networking	3,6	3

SEM WISE STRUCTURE

I Semester

SNO	COURSE CODE	COURSE NAME	Type	L	T	P	S	Cr	CH
1	20PY5101	Modern Pharmaceutical Analytical Techniques	PC	4	0	0	0	4	4
2	20PY5102	Drug Delivery Systems	PC	4	0	0	0	4	4
3	20PY5103	Modern Pharmaceutics	PC	4	0	0	0	4	4
4	20PY5104	Regulatory Affairs	PC	4	0	0	0	4	4
5	20PY5105	Pharmaceutics Practical I	PC	0	0	12	0	6	12
6	20PY5106	Seminar/Assignment	Skill	0	0	8	0	4	8
		Total		16	0	20	0	26	36

II semester

SNO	COURSE CODE	COURSE NAME	Type	L	T	P	S	Cr	CH
1	20PY5107	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	PC	4	0	0	0	4	4
2	20PY5108	Advanced Biopharmaceutics & Pharmacokinetics	PC	4	0	0	0	4	4
3	20PY5109	Computer Aided Drug Delivery System	PC	4	0	0	0	4	4
10	20PY5110	Cosmetic and Cosmeceuticals	PC	4	0	0	0	4	4
11	20PY5111	Pharmaceutics Practical II	PC	0	0	12	0	6	12
12	20PY5112	Seminar/Assignment	skill	0	0	8	0	4	8
		Total		16	0	20	0	26	36

III semester

SNO	COURSE CODE	COURSE NAME	Type	L	T	P	S	Cr	CH
13	20PY5113	Research Methodology and Biostatistics*	PC	4	0	0	0	4	4
14	20PY5114	Journal club	skill	0	0	2	0	1	2
15	20PY5115	Discussion / Presentation (Proposal Presentation)	skill	0	0	4	0	2	4
16	20PY5116	Research Work	skill	0	0	28	0	14	28
		Total		4	0	34	0	21	38

IV semester

SNO	COURSE CODE	COURSE NAME	Type	L	T	P	S	Cr	CH
17	20PY5117	Journal Club	skill	0	0	2	0	1	2
18	20PY5118	Research Work	skill	0	0	33	0	16	33
19	20PY5119	Discussion/Final Presentation	skill	0	0	6	0	3	6
20	20PY5120	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	skill	0	0	8	0	4	8
		Total		0	0	49	0	24	49