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## VISION

To be a globally renowned 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.







## Koneru Satyanarayana, Chancellor

Sri Koneru Satyanarayana, BE, FIE, FIETE, MIEEE graduated in Electronics and Communication Engineering in the year 1977. Along with Sri Koneru Lakshmaiah, he is the co-founder of the Institute which was established in the year 1980. He is an educationist of eminence and also an industrialist of great repute. He runs a number of industries in and around Vijayawada.

> Dr. K. S. Jagannatha Rao Pro-Chancellor

Prof. K. S. Jagannatha Rao was one of the leading scientists in neuroscience research in globe. He was the Director on Institute for Scientific Research and Technological Advances (INDICASAT AIP), Republic Panama and contributed lot in building innovation in higher education and research in Panama since 2010. He played a key role in building PRISM (Panamanian Research Institutes of Science and Medicine) in Latin America. Dr. Rao has his research area on Brain Research and established Alzheimer's Centre and published 165 papers in leading Biochemistry and Neuroscience Journals, supervised 19 Ph.D students. He is also adjunct faculty of Biomedical Informatics of UTHS, Houston, and Advisory Board Member of UT- EI Paso Minority Health NIH program, USA and Adjunct Faculty, Methodist Research Institute, Houston, USA. He was elected Member of Panamanian Association for the Advancement of Science (APANAC) - Considered as National Science Academy of Panama. He received his undergraduate and Ph.D degrees from Sri Venkateswara University, Tirupati. Later, joined in Central Food Technological Research Institute, Mysore. He received Sir C. V. Raman Award by Karnataka State Council of Science and Technology, 2003.





## Prof. G P S Varma Vice-Chancellor

Prof. G P S Varma, Vice-Chancellor, KLEF, is one of the most widely experienced leaders in Indian higher education, known for his commitment to expanding student opportunity, catalyzing academic innovation, and encouraging university's civic engagement and service to society. He adorned the position of Chairman, ISTE (Indian Society for Technical Education)- AP State, TSEMCET Test Committee Member-2021 nominated By Telangana State Govt, APEAMCET Admission Committee Member in 2016 by Andhra Pradesh State Council of Higher Education, Govt. of Andhra Pradesh. He has been a very farsighted Peer Team Visit Member for National Assessment and Accreditation Council (NAAC), Expert Committee Member for University Grants Commission (UGC) Autonomous Visits. He has been an Advisory Council Member for (CEGR) Centre for Education Growth, and Research India International Centre, New Delhi, and Board Member for Big-Data Analytics Forum.



## Dr. A. V. S. Prasad Pro-Vice Chancellor

Dr. A. V. S. Prasad, M.E and Ph.D from JNTU, Hyderabad is a professor in Civil Engineering. He has a rich experience of 33 years in academics which includes 26 years in administration at various cadres ranging from Head of Department, Dean, Principal, Director and Pro-Vice Chancellor. He has served as Director of Audisankara group of institutions and Narayana Group of Institutions for 18 years and was instrumental in getting these institutions accredited by NAAC, NBA, Autonomous and gained many laurels from the State Government, JNTU etc. He has served as Pro-Vice Chancellor of KL University for 3 years.

He has extensive knowledge of administrative system, maintaining statutory norms of bodies like AICTE, UGC etc and has a good understanding of NBA, NAAC procedures and norms. He served as Member, Chairman of Board of Studies at JNTU(A), KLCE(Autonomous) and KL University.

## Dr. Venkatram Nidumolu Pro-Vice Chancellor

Dr. Venkatram Nidumolu, Pro-Vice Chancellor is High performing, strategic thinking professional with more than 15years of administration experience and 20 years of teaching experience in KLEFand 30 years overall experience in the higher education sector. He graduated in B.Tech (ECE) from Acharya Nagarjuna University, pursued M.S degree from BITS, PILANI in software Systems. He received Ph.D award from Acharya Nagarjuna University. He held the positions like HOD, Joint Register, Principal, and Dean-Academics before becoming Pro-Vice Chancellor. He was core member of all NBA, NAAC, & other accreditations since 2004 and he has good experience in handling of quality issues and assessment related practices.



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SI No	Acronyms	Full Form
1	KLEF	Koneru Lakshmaiah Education Foundation
2	CET	Common Entrance Test
3	KLEEE	KLEF Engineering Entrance Examination
4	JEE	Joint Entrance Examination
5	BT	Biotechnology
6	CE	Civil Engineering
7	CS	Computer Science & Engineering
8	EC	Electronics & Communication Engineering
9	EE	Electrical & Electronics Engineering
10	СМ	Computer Engineering
11	ME	Mechanical Engineering
12	AD	Artificial Intelligence & Data Science
13	CI	Computer Science & Information Technology
14	CGPA	Cumulative Grade Point Average
15	SGPA	Semester Grade Point Average
16	LTPS	Lecture, Tutorial Practical, Skill
17	SEE	Semester-End Examinations
18	SIE	Semester-In Examinations
19	OJET	On-the-job Engineering Training
20	IRP	Industrial Relations and Placements
21	PS	Practice-School
22	OPAC	Online Public Access Catalog
23	QCM	Quality Circle Meeting
24	MOOC	Massive Open Online Course
25	MOU	Memorandum of Understanding
26	OD	On Duty
27	(A,B]	Between A and B excluding value A and including value B
28	COE	Controller of Examinations
29	VLSI	Very Large-Scale Integration
30	MTech	Master of Technology
31	COA	Council of Architecture
32	JEE	Joint Entrance Examination
33	NATA	National Aptitude in Architecture

## Acronyms

34	PC	Professional Core
35	BSAE	Building Science and Applied Engineering
36	PE	Professional Elective
37	PAECC	Professional Ability Enhancement Compulsory Courses
38	SEC	Skill Enhancement Course
39	OE	Open Elective
40	CTIS	Cloud Technology and Information Security
41	DS	Data Science
42	loT	Internet of Things
43	IPA	Intelligent Process Automation
44	B.B.A.,LL.B.	Bachelor of Business Administration and Bachelor of Laws
45	LL.B.	Bachelor of Laws
46	BCI	Bar Council of India
47	CLAT	Common Law Admission Test
48	НМ	Hotel Management
49	ВТК	Basic Training Kitchen
50	QTK	Quantitative Training Kitchen
51	АТК	Advanced Training Kitchen
52	MBA	Master of Business Administration
53	BBA	Bachelor of Business Administration
54	MSc (F&C)	Master of Science (Finance & Control)
55	BA	Bachelor of Arts
56	M.Sc.	Master of Science
57	PCI	Pharmacy Council of India
58	PY	Pharmacy
59	B. Com (H)	Bachelor of Commerce with Honors
60	ACCA	Association of Chartered Certified Accountants

## INTRODUCTION

The President of Koneru Lakshmaiah Education foundation, Er. Koneru Satyanarayana, along with Late Sri. Koneru Lakshmaiah, founded the K L College of Engineering in the Academic year 1980-81. With the mighty vision and restless efforts of Er. Koneru Satyanarayana K L College of Engineering carved a niche for itself through excellence in engineering education, discipline and record numbers of placements and was the leading college in the state of AP. K L College of Engineering achieved NBA Accreditation for all its B.Tech. Programs in 2004 and later reaccredited in 2007. K L College of Engineering was transformed into an autonomous engineering college in the year 2006. In 2008 this college received a record grade of 3.76 on a 4 points scale with "A" Grade from NAAC; and in February 2009, the college, and Accredited by National Assessment and Accreditation Council (NAAC) of UGC as 'A<sup>+++</sup>' with highest Grade of 3.57 CGPA on 4-point scale in 2018, through its founding society "Koneru Lakshmaiah Education Foundation" was recognized as Deemed to be University by the MHRD-Govt. of India, Under Section 3 of UGC Act 1956. This Deemed to be University is named as "KLEF".

## Location

KLEF is situated in a spacious 100-acre campus on the banks of Buckingham Canal of river Krishna, eight kilometers from Vijayawada city. Built within a rural setting of lush green fields, the institute is a virtual paradise of pristine nature and idyllic beauty. The campus has been aptly named "Green Fields" and the splendid avenue of trees and gardens bear testimony to the importance of ecology and environment. The campus ambience is most befitting for scholastic pursuits. The University is situated in a built-up area of around 15, 00,000 S.Ft.

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## Facilities

#### **Central Library: E-Resources**

The Central Library is the largest and holds materials to serve the whole University community.

It has materials relevant to the Engineering, Science & Humanities courses offered by the University.

The library system contains more than one lakh and fifty thousand books and periodicals on all subjects related to the teaching and research interests of the University staff and students. The library has over 36,000 electronic journal titles, academic databases and32.98 lakhs eBooks. Access is available on campus on student computers and remotely.

## The Data Centre

A State-of-the-Art Data center with advanced servers provides a highly interactive learning environment with full-fledged hardware and software training facilities.

## **Physical Education- Sports Facilities**

KLEF encourages students to explore their latent talents by providing good games and sports facilities. The institute is equipped with the following.

Sport/Game	No. of Courts	Sport/Game	No. of Courts
Athletic track	1	Handball Court	1
Hockey Field	1	Netball Courts	2
Badminton Courts	4	Throw ball courts	2
Tennikoit Courts	2	Beach Volleyball Court	1
Cricket Field with Net practice	3	Football Field	1
Volleyball Courts	2	Basketball Courts	2
Tennis Courts	2	Kabaddi Courts	2
Kho Kho Court	1	Table Tennis	6
Soft Ball	1	Chess	20
Archery	1	Caroms	12

The University had a State-of- the - Art Indoor stadium of 30000 sq.ft with:

- 4 wooden Shuttle Courts/ Basketball Court
- Yoga and Meditation Centre
- Dramatics
- 8 Table Tennis Tables
- Hobby Centre
- Gymnasium for Girls
- Gymnasium for Boys
- Multipurpose room with Chess, Caroms etc.
- Power lifting/Weightlifting

## **Accommodation- Hostels**

- KLEF has separate hostels for boys and girls with well furnished rooms and modern amenities.
- The overall atmosphere is very conducive for the students to concentrate on their studies.
- A state- of the- art kitchen and spacious dining area has been provided for both the hostels.
- Generators have been provided as power backup. Emphasis has been laid on hygiene and cleanliness for healthy living. A customized menu caters to the student needs, it keeps changing according to their tastes.
- Teaching staff will have to address the academic and personal problems of the students. Round-the-clock security, communication, dispensary facilities are also available.

## Facilities in the hostels

- Protected drinking water
- State of the art kitchen, dining hall
- Newspapers, telephones, toilets and bathrooms are well maintained.
- Every student in the hostel is provided with a cot, study table, chair and a rack.
- Fan and light are also provided in each room.
- Gas & Steam based hygienic food preparation.
- Palatable regional, national and international cuisines
- Cleanliness and Safety STD/ISD Facilities
- Medical Kits and First Aid Boxes Soft drinks, snacks, Fruits etc.
- Laundry Stationary shop

## **Hostel Rules and Regulations**

- Students are hereby informed that while staying in the hostel, it is essential to be responsible for maintaining dignity by upholding discipline.
- They must be obedient to the hostel warden/floor in –charges. Valuable items like jewelry etc. should not be kept with students while staying in the hostel.
- It is student's own responsibility to safeguard her/his Laptops, Money by locking suitcases and bags.
- If any loss is found, management will not take any responsibility. Students must intimate to the hostel authorities before giving police complaints against losses.
- Students are not allowed to indulge in smoking; consumption of Alcohol, Narcotic drugs etc., and defaulters will be strictly viewed upon.
- Students are directed that after locking their rooms they must hand over the keys to security and can collect them on returning to the hostel.
- Students must switch off Fans, Lights, Geysers, A/C's etc., before leaving their rooms.
- Visitors are not allowed inside the hostel at any time; however, they are allowed into the visitor's hall with the prior permission of the warden.
- Only family members listed by the parents are allowed to contact the student. Visiting hours are up to 7.30 pm only and after 7.30 pm visitors are required to leave the premises.
- Hostel students are not allowed to come into the hostel after 3.00 pm for morning shift students and 6.00pm for day shift students.
- Those students who are utilizing the computer lab, library etc., after the times specified must submit the permission slip to the security while entering the hostel.
- During public holiday outings, those who seek permission to leave the hostel will have to obtain written permission from the warden. Permission will be given only to those students who get permission from parents to leave the hostel during holidays/outings.
- Moving out of campus without permission is strictly prohibited. Strict study hours from 7.30 am to10.30 pm shall be maintained in the hostel.
- The hostellers must be in their allotted rooms during study hours. The general complaints of any kind should be noted in the complaint register, which is available at the hostel office.
- Registered complaints will only be entertained. Any health problem should be brought to the notice of Warden/Floor In charge for necessary treatment.

## Transportation

The institution runs 80 buses covering all the important points in Vijayawada City, Mangalagiri, Guntur & Tenali towns with a total seating capacity of 4000 students in two shifts. Transport is available 24 hrs, In case of any emergency in the institute /hostels. Transportation is available for conducting industrial tours and visits etc. Regular transport facility available up to 10PM.

## Healthcare

A full-fledged health center with all the facilities is established to cater the needs of the students, staff, Faculty and the public in the adopted villages. It consists of three doctors (Homoeopathy, Ayurvedic &Allopathy).

## Cafeteria

KLEF has a spacious canteen with the latest equipment and hygienic environment which provides quality food and prompts service and caters to the needs of all the students and staff. A central cafeteria of 1500 Sq.m. is available on the campus. Mini cafes and fast-food centers are available in various blocks. The canteen is open from 6:30 a.m. to 8:30 p.m. There is a wide variety of North-Indian and South-Indian cuisine and the students enjoy the pleasure of eating during the breaks. Cool aqua water for drinking is available.

## Placements

KLEF has meticulously planned to make all its outgoing students employed. The University had installed the infrastructure, employed well experienced faculty, designed and delivered programs that help to enhance the communication and soft skills which are required for making the students employable. An excellent system is in place that considers all the issues that make a student employable. The University has been successful for the last 7 years in employing all the students who have registered and eligible for placement through its offices located across the country. About 50 trained personnel work extensively to make the students ready for recruitment by the industry.

## **Counselling & Career Guidance**

A special Counseling Cell consisting of professional student counselors, psychologists, and Professors counsels/helps the students in preparing themselves to cope with studies, perform well in the tests & various competitions. This Cell provides its services to the students in getting the solutions for their personal problems and provides career guidance with the help of the Industrial Relations and Placements (IRP) department. A group of 20 students are allotted to each faculty member who counsels them regularly and acts as their mentor.

## **Social Service Wing**

KLEF has a social service wing which is used to channelize the social service activities of the faculty, staff and students. It has adopted 5 nearby villages and conducts activities like medical camps, literacy camps and educates the villagers regarding hygiene and health care on a regular basis.

## NSS/NCC wings

NCC/NSS is a credit course designed with an intent to transform NCC/NSS activities into curricular activities from an extracurricular thereby providing credits to students involved in NCC/NSS along with other attended advantages to the students in the university.

## **Hobby Clubs**

Wholly and solely managed by the students, contributed much to the cultural life of the campus and to the cultural evolution of the students. Few student bodies and clubs operate in the campus like music society, dance club, drama society, literary and debating club, English press club, drawing club, painting club, mime club, computer club etc. Students manage entire activities and budget of the organization for the entire semester in advance. Around 4000 students are active members of the Hobby Clubs.

## Life Skills and Inner Engineering

KLEF feels that it is its responsibility to mold the students as good human beings, contributing to the country and to society by producing responsible citizens. Along with the regular programs every student admitted into KLEF undergoes a one-week special life skills /orientation program. Through this program, KLEF is producing the students with clarity of thoughts and charity at heart. Strict

regularity, implicit obedience, courtesy in speech and conduct, cleanliness in dress. Life skills and inner engineering teach a student his/her obligation towards GOD, himself /herself his/her country and fellow human beings. Every student is encouraged to practice his/her own religious faith and be tolerant and respectful towards other religions.

## **Technical Festival**

KLEF organizes various programs for the all-round development of the students. The technical festival and project exhibition is organized in the odd semester (October) every year to elicit the innovative ideas and technical skills of the students.

## **Cultural Festival**

The cultural festival in the even semester (February) of every year is the best platform for the students to exhibit their talents and creativity. Through these festivals KLEF is imparting organizational skills, leadership skills, competitive spirit, and team behavior skills to our students. Along with the knowledge, KLEF festivals provide recreation to the student community.

## Center for Innovation, Incubation and Entrepreneurship (CIIE)

KLEF being a pioneering institute supporting Academics and Research in Engineering, Science and Technology is endowed with the entire infrastructure and highly experienced faculty, has a Centre for Innovation, Incubation and Entrepreneurship (CIIE) that comprises of: Innovation Centre which aims to inculcate a spirit of innovation. Incubation Centre which aims to incubate innovations through prototype product development. Entrepreneurship Development Centre (EDC) which aims at fostering entrepreneurial skills among the students.

#### About KL College of Pharmacy

KL College of Pharmacy offers pharmaceutical sciences, in association with other streams like biotechnology which in turn offers innumerable opportunities as chemist, druggist, and novel drug designers in the modern era. The strides taking place in nanotechnology, stem cell therapy, gene editing and several other innovative therapeutic techniques. Incumbents can establish their startups on diagnostic devices, surgical instruments, and medicines.

## 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.

## Hallmarks of KL College of Pharmacy

- Highly qualified, experienced, and dedicated faculty with teaching, research, and industrial expertise.
- Innovative pedagogical approaches to increase student participation, learning and critical thinking.
- Skills and Value-added courses with global certification.
- Campus Recruitment Training and Placements.
- Development of global environment among the students with more than 50% International students.
- > Well-equipped and sophisticated laboratories with state of art infrastructure.
- 100+ paper publications in peer reviewed good impact factor national and international journals indexed with Scopus, Web of Science SCI etc.
- 10+ book chapters with reputed international publishers like Elsevier, Wiler, Springer, Taylor & Francis.
- Over 30+ MoUs have been signed with top foreign Universities.

## PROGRAM EDUCATIONAL OBJECTIVES (PEOs) AND PROGRAM OUTCOMES (POs)

## Program Educational Objectives (PEOs)

PEO	DESCRIPTION
1	<b>Knowledge &amp; Understanding:</b> The pharmacy students should possess upon graduation, knowledge of pharmaceuticals, medication use and their safety and effectiveness.
2	<b>Skill:</b> The graduate should be able to demonstrate his skills in providing quality pharmaceuticals, drug information and therapy including legal and ethical aspects.
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 Outcomes (POs)

РО	DESCRIPTION
1	<b>Pharmaceutical Knowledge:</b> 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.
2	<b>Design/Development of solutions:</b> 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.
3	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.
4	<b>Environment and sustainability</b> : Understand the impact of the professional pharmaceutical solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
5	<b>Ethics</b> : Apply ethical principles and commit to professional ethics and responsibilities and norms of the pharmacy practice.
6	<b>Life-long learning</b> : 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 (PSOs)

PSO	DESCRIPTION
1	To impart knowledge and skills on criteria for formulation design, product development, in
	vitro & biopharmaceutical evaluation, and optimization for better therapeutic efficacy.
2	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

		Key Components of Mission			
		M1	M2	М3	M4
S. No	Description of PEOs	High quality Education	Community service	Research and Development	Entrepreneur ship
PEO1	Knowledge & Understanding: The pharmacy students should possess upon graduation, knowledge of pharmaceuticals, medication use and their safety and effectiveness.	✓ 	~		
PEO2	<b>Skill:</b> 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.			✓	

## PROGRAMS LIST AND ELIGIBILITY CRITERIA

## **UG Courses**

S.NO	NAME OF THE PROGRAM	DURATION (Years)
1	BACHELOR OF PHARMACY	4

## **PG Courses**

S.NO	NAME OF THE PROGRAM	DURATION (Years)
1	DOCTOR OF PHARMACY	6
2	MASTER OF PHARMACY	2

## Eligibility Criteria for Admission in M. Pharmacy

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.)

# ACADEMIC REGULATIONS

## Terminology

- Academic Council: The Academic Council is the highest academic body of the University and is responsible for the maintenance of standards of instruction, education and examination within the University. The Academic Council is an authority as per UGC regulations and it has the right to take decisions on all academic matters including academic research.
- Academic Year: It is the period necessary to complete an actual course of study within a year. It comprises of two consecutive semesters i.e., Even and Odd semester.
- Academic Pathways: Students of all programs of study are given the opportunity to choose their career pathways viz. Employability, Innovation and Research. Each of these pathways prepares the students in a unique way, enabling them to achieve the heights of their career.
- Academic Bank of Credits (ABC): It helps the students to digitally store their academic credits from any higher education institute registered under ABC in order to award Certificate / Diploma / Degree / Honors based on the credits earned by the student. All the credits acquired by the students are stored digitally by registering into Academic Bank of Credits (ABC) portal. It also supports retaining the credits for a shelf period and continue their program study with multiple breakovers.
- **Backlog Course:** A course is considered to be a backlog if the student has obtained a failure grade (F).
- **Betterment:** Betterment is a way that contributes towards improving the students' grade in any course(s). It can be done by either (a) re-appearing or (b) re-registering for the course.
- **Board of Studies:** Board of Studies (BOS) is an authority as defined in UGC regulations, constituted by Vice Chancellor for each of the department separately. They are responsible for curriculum design and update in respect of all the programs offered by a department.
- **Branch of Study:** It is a branch of knowledge, an area of study or a specific program (like Civil Engineering, Mechanical Engineering, Electrical and Electronics Engineering etc.,)
- **Certificate course:** It is a course that makes a student gain hands-on expertise and skills required for holistic development. It is a mandatory, non-credited course for the award of degree.
- **Change of Branch:** Change of branch means transfer from one's branch of study to another.
- **Compulsory course:** Course required to be undertaken for the award of the degree as per the program.
- **Course:** A course is a subject offered by the University for learning in a particular semester.
- **Course Handout:** Course Handout is a document which gives a complete plan of the course. It contains the details of the course viz. Course title, Course code, Pre-requisite, Credit structure, team of instructors, Course objectives, Course rationale, Course Outcomes and the relevant syllabus, textbook(s) and reference books, Course delivery plan and session plan, evaluation method, chamber consultation hour, course notices and other course related aspects. In essence, course handout is an agreement between students (learners) and the instructor.
- **Course Outcomes:** The essential skills that need to be acquired by every student through a course.
- **Credit:** A credit is a unit that gives weight to the value, level or time requirements of an academic course. The number of 'Contact Hours' in a week of a particular course determines

its credit value. One credit is equivalent to one lecture hour per week or two hours per week of tutorials/ self-learning/ practical/ field work during a semester.

- Credit Point: It is the product of grade point and number of credits for a course.
- **Credit Transfer:** The procedure of granting credit(s) to a student for course(s) undertaken at another institution.
- **Choice Based Credit System:** The institute adopts Choice Based Credit System (CBCS) on all the programs offered by it which enables the students to choose their courses, teachers and timings during their registration. This enables the students to decide on the courses to be done by them in a specific semester according to their interests in other activities.
- **Cumulative Grade Point Average (CGPA):** It is a measure of cumulative performance of a student over all the completed semesters. The CGPA is the ratio of total credit points secured by a student in various courses in all semesters and the sum of the total credits of all courses in all the semesters. It is expressed upto two decimal places.
- **Curriculum:** Curriculum is a standards-based sequence of planned experiences where students practice and achieve proficiency in content and applied learning skills. Curriculum is the central guide for all educators as to what is essential for teaching and learning, so that every student has access to rigorous academic experiences.
- **Course Withdrawal:** Withdrawing from a Course means that a student can drop from a course within the first week of the odd or even Semester (there is no withdrawal for summer semester). However, s/he can choose a substitute course in place of it by exercising the option within 5 working days from the date of withdrawal.
- **Degree:** A student who fulfils all the Program requirements is eligible to receive a degree.
- **Degree with Specialization:** A student who fulfills all the Program requirements of her/his discipline and successfully completes a specified set of Professional elective courses in a specialized area is eligible to receive a degree with specialization.
- **Department:** An academic entity that conducts relevant curricular and co-curricular activities, involving both teaching and non-teaching staff and other resources.
- **Detention in a course:** Student who does not obtain minimum prescribed attendance in a course shall be detained in that course. Refer to Attendance & Detention Policy
- **Dropping from the Semester:** A student who doesn't want to register for the semester should do so in writing in a prescribed format before commencement of the semester.
- **Evaluation:** Evaluation is the process of judging the academic work done by the student in her/his courses. It is done through a combination of continuous in-semester assessment and semester end examinations.
- **ERP:** ERP (Enterprise Resource Planning) system is a comprehensive software solution designed to streamline and automate various administrative, academic, and financial processes within the University. It manages student information, including admissions, registration, enrollment, attendance, grades, and academic records.
- **Grade:** It is an index of the performance of the students in a said course. Grades are denoted by alphabets.
- **Grade Point:** It is a numerical weight allotted to each letter grade on a 10 point scale.
- Industrial Visit: Visit to a company/firm as per the academic requirement.
- In-Semester Evaluation: Summative assessments used to evaluate student learning, acquired skills, and academic attainment during a course.
- LMS: LMS stands for Learning Management System. It is a platform used in the institution to manage and deliver courses. Students can access learning resources, participate in online

discussions, submit assignments, take assessments, and communicate with their instructors and peers.

- **Make-up Test:** An additional test scheduled on a date other than the originally scheduled date.
- **Practice School:** It is a part of the total program and takes one full semester in a professional location, where the students and the faculty get involved in finding solutions to real-world problems. A student can choose Project/Practice School during his/her 7<sup>th</sup> or 8<sup>th</sup> semester of his/her Academic Year to meet the final requirements for the award of B.Tech degree.
- **Pre-requisite:** A course, the knowledge of which is required for registration into higher level course.
- **Professional Core:** The courses that are essential constituents of each engineering discipline are categorized as Professional Core courses for that discipline.
- **Program:** A set of courses offered by the Department. A student can opt and complete the stipulated minimum credits to qualify for the award of a degree in that Program.
- **Program Outcomes:** Program outcomes are statements that describe what students are expected to know or be able to do at the end of a program of study. They are often seen as the knowledge and skills students will have obtained by the time, they have received their intended degree.
- **Program Educational Objectives:** The broad career, professional, personal goals that every student will achieve through a strategic and sequential action plan.
- **Project:** Course that a student has to undergo during his/her final year which involves the student to undertake a research or design, which is carefully planned to achieve a particular aim. It is a credit-based course.
- **Supplementary**: A student can reappear only in the semester end examination for the Theory component of a course, subject to the regulations contained herein.
- **Registration**: Process of enrolling into a set of courses in a semester/ term of the Program.
- **Re-Registration:** Student who are detained in courses due to attendance or marks criteria as per their regulation are given a chance to re-register for the same and complete it during the summer term.
- Semester: It is a period of study consisting of 16<u>+</u>1 weeks of academic work equivalent to normally 90 working days including examination and preparation holidays. The odd Semester starts normally in July and even semester in December.
- Semester End Examinations: It is an examination conducted at the end of a course of study.
- Single Section Course: Course taught for a single section.
- **Social Service:** An activity designed to promote social awareness and generate well-being; to improve the life and living conditions of the society.
- **Student Outcomes:** The essential skill sets that need to be acquired by every student during her/his program of study. These skill sets are in the areas of employability, entrepreneurial, social and behavioral.
- **Summer term:** The term during which courses are offered from May to July. Summer term is not a student's right and will be offered at the discretion of the University.

#### Academic Instructions

#### **General Behaviour**

- Student should communicate in English with faculty and other students while he/ she is in campus.
- Students are expected to wish/greet all officials of the KLEF with due respect.
- Students should be courteous and polite while communicating with all Faculty & staff.
- Students should maintain silence and/or speak in a polite way in and around the classrooms, library, laboratories, and offices of the Deans, Program Chairs, Senior Officials, faculty rooms and corridors of academic buildings.
- It must be noted that shouting, talking in loud voice or in chorus, using indecent, abusive and discourteous language anywhere within the institution premises are considered serious acts of indiscipline and are punishable.
- Students should not loiter during the free time in the university campus.
- Students should not issue any public or press statement, send letters to editors, government, public servants or notaries without prior permission and approval of the Registrar of KLEF in writing.
- Students should keep the status, dignity, prestige and reputation of KLEF high and not engage in anything that might directly or indirectly undermine the standing of the institution.
- Students must always adhere to a prescribed/decent dress code befitting the dignity of a technical/professional student within the campus.
- Ragging of any student is a serious act of indiscipline and has been totally banned by the Hon'ble Supreme Court of India.
- A student found involved in any form of ragging, verbal or physical, inside or outside the institutional campus, hostels, or buses shall be treated as per the anti-ragging rules of the KLEF.
- Students must not be involved in quarrelling or fighting or any indecent verbal or physical activity among themselves, or with staff and faculty or visitors.
- Direct or indirect involvement in any such activity will be considered as serious breach of discipline and strict disciplinary action will be taken against the students that engage in such activities.
- Students are not allowed to sit on the steps, boundary walls on the higher floors of any building, or engage in gossiping, making noise or any other such activity.

KLEF Working Hours: KLEF operates between 7:20 AM to 5.00 PM (in shifts) on all weekdays.

**Class Environment:** The institute is a community of learners. Students have a responsibility of creating and maintaining an environment that supports effective learning to receive effective instructions in classrooms and laboratories. KLEF expects students to conduct themselves in an orderly and cooperative manner by adhering to University Rules & Regulations.

#### **Laboratory Environment**

# A conducive learning environment in the laboratory is essential and the students are advised to follow the guidelines mentioned below:

- Always listen carefully to the faculty especially for the safety precautions to take in the laboratories.
- Accidents resulting in injuries may occur if precautions are not taken.
- Eating in laboratories is strictly prohibited.
- Proper dress code is to be followed as prescribed by faculty in each lab.
- Students should familiarize themselves with the location of all the safety equipment which may be available.
- Follow evacuation procedures quickly and quietly, if needed.
- Students should always conduct themselves in a responsible and cautious manner. Risky behaviours such as pushing, running, jumping etc., are unwarranted.
- Only materials required to complete and record the experiment instructions, (e.g., pencils or graph paper, etc.) should be brought into the laboratory.
- Equipment must be carefully handled to prevent breakage or damage, otherwise appropriate penalties/disciplinary-action may believe/imposed.
- Lab station must be cleaned prior to leaving a lab.
- Any accident, no matter how small or big, must be reported to the concerned faculty immediately.

#### **Registration Process**

- For every course, the student must undertake the registration process prior to commencement of the coursework, based on the following conditions.
- Registration into a course will be permitted only for such courses, which are offered by KLEF in that semester.
- A student must clear the pre-requisite(s) if any, to register into a course.
- KLEF reserves the right to register.
- Registration for add/drop/change of a course will be permitted only within one week from the scheduled date of commencement of classes.
- Students can register up to a maximum of 32 credits of their choice in a semester to meet their program requirements.
- Students, who wish to register for additional credits through Overloading or less credits through Under loading, must seek prior permission from Dean- Academics.
- Students who have opted for minor degree, Honours degree, can register for a greater number of credits in a semester through Overloading (subjected to guidelines appropriate to compliance on eligibility).
- KLEF reserves the right to withdraw within one week of the commencement of the semester any elective course offered, if adequate number of students have not registered or for any other

administrative reasons. In such cases, the students are permitted to register for any other elective course of their choice provided they have fulfilled the eligibility conditions.

- KLEF reserves the right to cancel the registration of a student from a course or a semester or debar from the degree on disciplinary / plagiarism grounds.
- A student is solely responsible to ensure that all conditions for proper registration are satisfied. If, there is any clash in the timetable, it should be immediately brought to the notice of the Department Year coordinator for necessary corrective action.
- The registration may be cancelled for a course or the entire semester either by KLEF if any irregularity is found at a later stage.

#### **Student Course Registration Process:**

To complete the student registration, student login to new ERP portal with their valid login credentials. After login student should click on Academic Registrations Student Course Registration. Now Student can view the courses and sections in dropdown menus. Student can select the sections against the courses on their own choice. Student can view the timetable on top of the selection of each course and section.

## PROGRAM CURRICULUM

For an academic program the curriculum is the basic framework that will stipulate the credits, category, course code, course title, course delivery (Lectures / Tutorials / Practice / Skill / Project/ Self Study / Capstone Design etc.), in the Choice Based Credit System. However, all such are essentially designed, implemented and assessed in Outcome Based Education Framework.

## Program Structure:

- An Academic Year is made of two semesters each is of, approximately 16<u>+</u>1 week duration and each semester is classified as:
  - Odd Semester (September to January)
  - Even Semester (January to June).
- KLEF may offer summer term between May and June.
- Students have the flexibility to choose courses of their own choice prescribed by the institution.
- Student can register for a maximum of 30 credits, other than audited and certificate courses per semester. This is not applicable when student exercises the overloading option (while doing project work / practice school / Minor degree / Honors degree program / specialization).

SI No	Course Category	Min. Credits	
1	HAS	NA	
2	BSC	NA	
3	ESC	NA	
4	PCC	48	
5	FCC	NA	
6	SDC	19	
7	PEC	NA	
8	PRI	30	
9	OEC	NA	
10	VAC	NA	
11	AUC	NA	
12	SIL	NA	
GRAD REQUIREMENTS		97	

## **Course Structure:**

- Every course has a Lecture-Tutorial-Practice-Skill (L-T-P-S) component attached to it.
- Based upon the L-T-P-S structure the credits are allotted to a course using the following criteria.
  - Every 1 hour of Lecture / Tutorial session is equivalent to one credit.
  - Every 2 hours of Practical session is equivalent to one credit.
  - Every 4 hours of skill-based practice is equivalent to one credit.
  - 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.

## **Course Classification:**

Any course offered under M. Pharmacy program is classified as:

- **Professional Core Courses (PCC):** Professional core courses are a set of courses that are essential for all engineering students. These courses provide students with the knowledge and skills they need to be successful in their chosen engineering discipline.
- Skill Development Courses (SDC): Skill development courses can provide students with the knowledge and skills they need to use specific software or hardware. This can be especially important for students who are interested in pursuing a career in a particular field.
- Project Research & Internships (PRI): Project, Research and Internships can help students gain a better understanding of their chosen field by giving them the opportunity to apply their knowledge and skills to real-world problems. These can help students explore their interests by giving them the opportunity to work on projects that they are passionate about.

## **Course Precedence:**

The following are the guidelines for registering into courses with pre-requisites.

- Every course may have one or more of its preceding course(s) as pre- requisite(s).
- To register for a course, the student must successfully be promoted in these course(s) earmarked as pre-requisite(s) for that course.

## Summer Term Courses:

KLEF offers summer term courses during May and June. The following are the guidelines to register in to courses offered in Summer Semester.

- A student may register for course/s in each summer term by paying the stipulated fee.
- Students registering for more than one (1) summer course must ensure that there is no clash in the time table.
- A student can register into a detained course or a not-registered course (course offered in regular semester, but student failed to register due to the non- compliance of pre-requisite condition but has paid the fee.) A student can also register for other than the above two mentioned categories of courses only if they are permitted for acceleration.
- In any case, a student can register only for a maximum of 12 credits during summer term.
- Attendance & Promotion policy for summer term is same as compared to the regular semester except for condonation policy. Condonation is not applicable for summer term courses.

## REQUIREMENTS FOR THE AWARD OF DEGREE

The student is awarded a M. Pharmacy degree provided she/he

- Must successfully earn a minimum of 97 credits, as stipulated in the program structure.
- 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.
- Must successfully complete the research project.
- Must have successfully obtained a minimum CGPA of 5 at the end of the program.
- Must have finished all the above-mentioned requirements in less than twice the period mentioned in the Academic structure for each program, which includes deceleration period chosen by the student, deceleration imposed by KLEF or debarred from the KLEF.

Regulation	Measure	Min. Requirement
Min Credits	Credits	97
Min CGPA	CGPA	5
SGPA Consistency	NA	NA
Value Added Courses	#Courses	1
Audit Courses	#Courses	NA
Audit Courses for Career Enhancement	#Courses	NA
Specialization Stream	NA	NA
Social Internship	#weeks	NA
Technical Internship	#weeks	NA
SDC Stream	NA	NA
Course Modes (Mode A   Mode P)	NA	NA

## Award of Degrees

A student having cleared all the courses and met all the requirements for the award of degree with:

- 1. Minimum of 5 CGPA is considered as Pass category
- 2. CGPA of 7.5 and above will be awarded First class with Distinction provided the student has cleared all the courses in first attempt and must have fulfilled all the program requirements within the specified minimum years duration.
- 3. CGPA of 6.00 to 7.49 will be awarded First class
- 4. CGPA of 5.00 to 5.59 will be awarded Second class

## ATTENDANCE RULES AND DETENTION POLICY

#### Attendance policy for promotion in a course:

The student must maintain a minimum attendance of 85% in every course. In case of medical exigencies, the student/parent should inform the principal within a week by submitting necessary proofs and in such cases the attendance can be condoned up to an extent of 10%. by Principal on the recommendation of the Head of the Department.

- Attendance in a course shall be counted from the date of commencement of the classwork.
- Attendance for the students who are transferred from other institutes and for new admissions, attendance must be considered from the date of her/his admission.
- In case of attendance falling marginally below 75% due to severe medical reasons or any other valid reasons, the Principal/Program chair may bring such cases, along with valid and adequate evidence, to the notice of the Dean Academics. The condonation board formed by Vice-Chancellor under the chairman ship of Dean-Academics will consider any further relaxation in attendance from the minimum attendance percentage requirement condition after going through case by case.

## Attendance based Marks:

As per the PCI guidelines there are certain marks for attendance to be awarded for each subject and it is clearly reflected in the respective course handouts which should duly be approved by the Dean Academics. For any course, not more than 5% marks can be allotted for attendance.

For M. Pharm (Theory courses) the distribution of marks, if the attendance percentage is 95-100 is 8 marks, 90-94 is 6 marks, 85-89 is 4 marks, 80-84 is 2 marks and <80 is 0 marks. Further, for M. Pharm (Practical Courses) the distribution of marks, if the attendance percentage is 95-100 is 10 marks, 90-94 is 7.5 marks, 85-89 is 5 marks, 80-84 is 2.5 marks and <80 is 0 marks.

Attendance Waiver: Students maintaining a CGPA  $\ge$  9.00 and SGPA  $\ge$  9.00 in the latest completed semester get a waiver for attendance in the following semester. Students who thus utilize an attendance waiver will be awarded the marks allocated for attendance (if any) based on their performance in an advanced assignment specified by the course coordinator (emerging topics related to the course). S/he can appear in all assessments and evaluation components without being marked ineligible due to attendance-based regulations.

Attendance Condonation for Participation in KLEF / National / International Events: Only those students nominated / sponsored by the KLEF to represent in various forums like seminars / conferences / workshops / competitions or taking part in co- curricular / extra- curricular events will be given compensatory attendance provided the student applies in writing for such a leave in advance and obtain sanction from the Principal basing on the recommendations of the Head of the Department (HoD) for academic related requests; or from the Dean Student Affairs for extracurricular related requests. For participation in the KLEF's placement process the names of students will be forwarded by the placement cell in-charge to the respective Heads of the Departments. Students participating in KLEF/National/International events like technical fests, workshops, conferences etc., will be condoned

for 10% of total classes conducted for each course in the semester. This condonation is not applicable for summer term.

## **Course Based Detention Policy:**

In any course, a student must maintain a minimum attendance as per the **attendance policy for promotion in a course**, to be eligible for appearing in the Sem-End examination. Failing to fulfill this condition, will deem such student to be detained in that course and become ineligible to take semester end exam.

## Eligibility for appearing Sem – End Examination:

A Student registered for a course and maintained minimum attendance of 85% is eligible to write the Semester-End Examination for that course unless found ineligible due to one or more of the following reasons:

- Shortfall of attendance
- Detained
- Acts of indiscipline
- Withdrawal from a course

## ASSESSMENT AND EVALUATION PROCESS

The assessment is conducted in formative and summative modes with a weightage of 25% for Semester-In evaluation and 75% for Semester-End Evaluation.

The distribution of weightage for various components of formative and summative modes are decided and notified by the course coordinator through the course handout after approval by the Dean Academics, prior to the beginning of the semester. Students are advised to refer the course handout to get more detailed information on assessment.

- Sem-In examinations and the Semester-End Examinations will be conducted as per the Academic Calendar.
- Students may have to take more than one examination in a day during Sem-In exams, Semester-End Examinations /Supplementary examinations.
- Examinations may be conducted on consecutive days, beyond working hours and during holidays.

## Semester-In Evaluation

The following are the guidelines for the Semester-In evaluation.

- The process of evaluation is continuous throughout the semester. The distribution of marks for Semester-In evaluation is 25% of aggregate marks of the course.
- To maintain transparency in evaluation, answer scripts are shown to the students for verification, within one week of conduct of exam. If there is any discrepancy in evaluation, the student can request the course-coordinator to re-evaluate.
- The solution key and scheme of evaluation for all examinations are displayed by the Course-Coordinator in the appropriate web portal of the course, on the day of the conduct of examination.
- In case the student is unable to appear for any evaluation component owing to hospitalization, participation in extra/ co-curricular activities representing KLEF/ state/ country; the Dean Academics can permit to conduct of re- examination for such students.
- In case a student has missed any of the two in-semester evaluations, S/he is eligible for and will be provided with an opportunity of appearing for re- examination.

## Semester End Examination

- The distribution of marks for Semester-End evaluation is 75% of aggregate marks of the course
- The pattern and duration of Sem End examination are decided and notified by the Course Coordinator through the Course handout, after approval from the Dean Academics.
- To maintain transparency in evaluation, answer scripts are shown to the students for verification. If there is any discrepancy in evaluation, the student can request the Controller of Examinations to re-evaluate.
- If a student earns 'F' grade in any of the courses of a semester, an instant supplementary exam (for only Semester End Exam component) will be provided within a fortnight of the declaration of the results.

## Assessment of Project/Research-Based Subjects

All project or research-based subjects must have a defined time limit for completion. The specific time limits and schedule for monitoring and evaluating student performance will be announced each term. The final project report, after obtaining a plagiarism certificate, will be considered, and evaluated by the panel of examiners. Student project reports must follow the guidelines prescribed by the Dean of Academics.

## Absence in Assessment & Examination

If a student fails to take any formative assessment component (due to ill-health or any valid reason), no second chance will be given, and zero marks will be awarded for the same. In cases of excused absence, the instructor may provide an opportunity to the student to reappear in quizzes or assignments or any other internal assessment criteria based on the approval from the principal & the concerned Head of the Department in written. If a student fails to write Sem-In Exam-I or obtained less than 50% marks in Sem-In Exam-I, he must attend remedial classes and maintain a minimum 85% of attendance in remedial classes to be eligible for Make-up test for Sem-In exam-I. Further, the number of remedial classes to be conducted shall be 50% of regular classes held till the Sem-In exam-I. However, there is no make-up test for Sem-In Exam-II or for the Laboratory exams.

A student's absence for Sem-In exams under the following circumstances are only considered for makeup test.

- Pre-approved participation in University/State/National/International co- curricular and extra-curricular activities
- Ill health and medical emergencies for the student leading to hospitalization with certification by the doctor stating inability of student to attend Sem-In exams clearly within the necessary dates.
- Death of immediate family member

## **Remedial Classes & Remedial Exam**

## The following categories of students are recommended to attend Remedial classes:

- Students who did not attend or obtain a minimum of 50% marks in the Sem-In examination-1
- Students for whom the learning objectives of CO1/CO2 are not attained in the Sem-In examination-1
- Any other student may also be permitted to attend remedial classes as per the discretion of the Principal.

## The following are the guidelines to conduct remedial classes:

- Remedial classes are scheduled to be conducted usually one- or two- weeks after the conclusion of Sem-In exam-1.
- The number of remedial classes to be conducted shall be 50% of regular classes held until the Sem-In exam-I.
- Remedial classes MUST NOT be scheduled during regular class work hours.

## The following are the guidelines for remedial exams:

- Students attending remedial classes must maintain attendance of minimum 80% in classes conducted under remedial classes, without fail for being eligible for attending remedial exam.
- After conduction of remedial test, the Sem-in exam-1 marks will be updated by considering the weightage of 75% of marks obtained by student in remedial exam, and 25 % of marks obtained by student in regular exam; with a CAP of 75% in overall marks.

## **Grading Process**

At the end of all evaluation components based on the performance of the student, each student is awarded grade based on absolute/relative grading system. Relative grading is only applicable to a section of a course in which the number of registered students is greater than or equal to 25. Choice of grading system is decided by the Course-Coordinator with due approval of Dean Academics and is specified in the course handout.

## **Absolute Grading**

Performance	Letter Grade	Grade Point	Percentage of marks				
Outstanding	0	10	90-100				
Excellent	A+	9	80-89				
Very Good	А	8	70-79				
Good	B+	7	60-69				
Above Average	В	6	50-59				
Average	С	5	46-49				
Pass	Р	4	40-45				
Fail	F	0	0-39				
Absent	AB	0	Absent				

The list of absolute grades and its connotation are given below

## SGPA & CGPA

The SGPA is the ratio of sum of the product of the number of credit s with the grade points scored by a student in all the courses and the sum of the number of credits of all the courses undergone by a student, in a semester.

Where 'Ci' is the number of credits of the i<sup>th</sup> course and 'Gi' is the grade point scored by the student in the i<sup>th</sup> course.

The CGPA is also calculated in the same manner considering all the courses undergone by a student over all the semesters of a program, where 'Si' is the SGPA of the i<sup>th</sup> semester and 'Ci' is the total number of credits in that semester.

- The SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.
- CGPA can be converted to percentage of marks: 10 X CGPA -7.5
- A student appearing for a course having lab integrated with theory and in case obtains less than 40% in either of lab or theory component of semester end examination, and in such case the student must reappear for the component only in which he has

secured less than 40%. Till successful attainment of minimum 40% of both components, the student remains in the F grade for that course.

- Audit/Certificate courses are graded as satisfactory (S) or non- satisfactory (NS) only.
- At the end of each semester, the KLEF issues a grade sheet indicating the SGPA and CGPA of the student. However, grade sheets will not be issued to the student if he/she has any outstanding dues.

#### Illustration of Computation of SGPA and CGPA

#### **SGPA Computation**

Course	Credits	Grade Letter	Grade Point	Credit Point (Credit X Grade)	
Course 1	3	А	8	3 X 8 = 24	
Course 2	4	В+	7	4 X 7 = 28	
Course 3	3	В	6	3 X 6 = 18	
Course 4	3	0	10	3 X 10 = 30	
Course 5	3	С	5	3 X 5 = 15	
Course 6	4	В	6	4 X 6 = 24	
	20			139	

Thus, SGPA =139/20 =6.95

#### **CGPA** Computation

Item	Semester						
	I	II	III	IV	V	VI	
Credits	20	22	25	26	26	25	
SGPA	6.9	7.8	5.6	6.0	6.3	8.0	

Thus,

 $CGPA = \frac{(20*6.9+22*7.8+25*5.6+26*6.0+26*6.3+25*8.0)}{(20+22+25+26+26+25)} = 6.73$ 

## Betterment

A student may reappear for semester end examination for betterment only in the theory part of the course for improving the grade, subject to the condition that, the student has passed the course, his/her CGPA is  $\leq$  6.75 and the grade in the respective course to be equal to or lower than "C". In the case of reappearing for a course, the best of the two grades will be considered. A Student can reregister in any course in any semester during the program for improvement of grade if the current grade in the course is lower than B+ and with due approval from Dean Academics in accordance with academic regulations. A student cannot reappear for semester end examination in courses like Industrial Training, courses with their L-T/ST-P-S Structure like 0-0-X-X, Project, Practice School and Term Paper.

## PROMOTION

## Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment.

## **Credit Transfer**

Credit transfer from other institutions to KLEF or vice versa is permitted.

## Rustication

A student may be rusticated from the KLEF on disciplinary grounds, based on the recommendations of any empowered committee, by the Vice Chancellor.

## Award of Medals

KLEF awards Gold and Silver medals to the top two candidates in each program after successful completion of their study. The medals are awarded based on their CGPA during the Annual Convocation with the following constraints:

a. The grade obtained through betterment/ supplementary will not be considered for this award.

b. S/he must have obtained first class with distinction for the award of Gold or Silver-medal.

## Academic Bank of Credits:

ABC helps the students to digitally store their academic credits from any higher education institute registered under ABC in order to award Certificate/Diploma/Degree/Honors based on the credits earned by the student. All the credits acquired by the students are stored digitally by registering into Academic Bank of Credits (ABC) portal. It also supports retaining the credits for a shelf period and continue their program study with multiple breakovers. Students may exit from their current program of study due to any unforeseen reasons or to focus on their chosen career path. In such cases, the student may break for a period of time (preferably not in the middle of an academic year) and may continue with the program of study at a later stage. Moreover, students must be able to complete their program by not exceeding the maximum duration of the program. If not, they may be issued with a Certificate, diploma, degree or honors based on the credits acquired over the period of time for all the programs approved by UGC.

## STUDENT COUNSELLING AND FEEDBACK

## Student Counselling

## **Academic Counselling Board**

Academic Counselling Board is constituted by the Dean Academics. This board shall comprise of the Chairman, Convener, Principal/Director, HOD and Professor/Associate Professor.

## A student will be put under Academic Counselling Board in the following circumstances:

- 1. Has CGPA of less than 6.00.
- 2. Has 'F' grade or 'Detained' in multiple courses.

The first level of Counselling such students will be done by the Mentor of the student and the HoD followed by the ACB and the list of students who have to undergo the ACB counselling be forwarded by the HoD to the Office of Dean Academics.

The students undergoing the Academic Counselling Board process may be allowed to register only for a few courses based on the recommendation of Academic Counselling Board.

## **Counselling Policy**

Student counselling takes great place in K L University. Counselling is designed to facilitate student achievement, improve student behaviour, subject analysis levels, attendance, and help students develop socially, professionals with bachelor's, master's degrees or beyond. Faculty counsellors provide counselling and serve an educational role in K L University. We have Mentors, Academic, Career, Physiological, Co-Curricular & Extra-Curricular activities counsellors in order to support students who are experiencing personal or academic challenges, help students choose careers and plan for university and intervene when students face behavioural, physical, or mental health challenges.

## **Academic Counselling**

- 1. Counsellor shall acquire backlog data and record the same into the counselling sheets.
- 2. Counsellor will acquire data about the attendance and performance in the internal evaluation and record them into the counselling data sheet.
- 3. Counsellors shall counsel the students regularly to track the performance of the students.
- 4. The counselling data sheet shall be submitted to the principal for verification and approval.
- 5. At the end of the semester a summary report will be sent to Dean Academics Office.

## **Career Counselling**

- 1. Counsellor has to take SWEAR analysis data in first year.
- 2. Counsellor shall acquire the data related to performance of the students in all the soft skills and other courses that contributes towards employability/ entrepreneurship/ career advancement the career counselling data sheets.

- 3. Counsellor will acquire data about the attendance and performance of the students during all the placement drives conducted by KLU and records the same into the counselling sheet.
- 4. Counsellors shall counsel the students regularly when the performance of the student is found be un-satisfactory.
- 5. The counselling sheet shall be verified by principal and corrective actions if any will be recommended to the respective departments.
- 6. At the end of the semester a summary report will be sent to Dean Academics Office.

## **Psychological Counselling**

- 1. Counsellor shall acquire data pertaining to psychological status of the students and record the same into the counselling sheets.
- 2. Counsellor will acquire data about the attendance and performance in the internal evaluation and record them into the counselling sheet and see whether the performance is in any way related.
- 3. Counsellor shall counsel the students regularly when the performance of the student is found to be un-satisfactory.
- 4. Counsellors should identify the need of any therapy required.
- 5. Once it is identified, the counsellor will arrange the treatment according to the psychological status of the student.
- 6. Counsellor should maintain the progression level of the student periodically.
- 7. The counselling sheet shall be verified by principal and corrective actions if any will be recommended to the respective departments.
- 8. At the end of the semester a summary report will be sent to Dean Academics Office.

## The duties of counsellors

**Mentoring:** Plan and design a system for student behavior, mental health and academic challenges, define structural and functional characteristics of the system in detail, plan provisions for academic mentoring apart from classroom interaction.

Academic Counselling: Develop a systematic and process-oriented mechanism to improve academic counselling in relation to student attendance, punctuality, performance of students in internal and semester examinations, course / program to be enrolled based on the strength and weakness of the student.

**Career Counselling:** Conduct personality test (SWEAR) to find suitable career path, create awareness on the job opportunities, career paths that exist in a specific discipline.

**Psychological Counselling:** Organize and strengthen the student counselling services, engage qualified and experienced mentors and advisories for each class of students for providing psychological guidance as required.
#### Guidance on Co-Curricular & Extra-Curricular activities

Form student clubs to give train and encourages the students to improve their skills, physical fitness and mental strength.

#### **Counselling Procedures**

- The HOD will allot 20 Students once admitted into a program to a faculty with allocation priority commencing from professors and onwards.
- > The faculty concerned will be called a counsellor/mentor.
- One hour per week will be allocated by the departments to enable the counsellors to counsel the students on various aspects.
- The counsellor will maintain a separate sheet to record student performance and also different kinds of counselling undertaken.
- Counsellor shall communicate with parents through mail, SMS and also through telephonic conversations. Student's attendance, marks, placement etc. data must inform to parents once in a month.
- > The communication undertaken shall be recorded in a separate register.

#### **Feedback System**

At KLEF, monitoring of feedback is a continuous process. Feedback is obtained from students and parents on various aspects. Feedback is taken through personal interaction with students, interaction with parents in addition to mid-semester and end-semester feedback. The institution assesses the learning levels of the students, after admission and organizes special programs for advanced learners and slow learners.

#### Feedback Types

In first year SWEAR analysis is done for every student in such a way it identifies their interests, preexisting knowledge, aspects to improve technical and logical skills based on their career choice.

#### The following are the different types of feedback taken at regular intervals:

- 1. Student General Feedback (Twice in a Sem.)
- 2. Student Satisfaction Survey (Once in a Sem.)
- 3. Student Exit Feedback (Once in a Year)
- 4. Academic Peers Feedback on Curriculum (Once in a Sem.)
- 5. Parents Feedback on Curriculum (Once in a Sem.)
- 6. Alumni Feedback on Curriculum (Once in a Sem.)
- 7. Industry Personnel Feedback on Curriculum (Once in a Sem.)
- 8. Student Feedback on Curriculum (Once in a Sem.)
- 9. Faculty Satisfaction Survey (Once in a Sem.)
- 10. Parent Teacher Association (Once in a Sem.)

#### **Feedback Procedure**

- General Feedback to be taken from the students on the aspects like Course Contents, Teaching Learning Process, Outcomes, Resources and Evaluation twice in every semester (Mid semester and End Semester Feedback) in a structured format floated by dean academics office.
- Student Satisfaction Survey (SSS) to all innovative methods and approaches should be recorded at appropriate intervals and the process should be refined based on that. Students should be sensitized on the process and methods and their understanding of the same should be assured.
- Exit survey feedback to be taken from the final year students on the aspects like entrance test, admission process, Course Contents, Teaching Learning Process, Outcomes, Resources and Evaluation, placements etc.
- Structured feedback for design and review of syllabus semester wise / year wise is received from Students, Alumni, Peers, Parent, Industry Personnel.
- Satisfaction Survey to be taken from the existing faculty on Course Contents, Teaching Learning Process, Outcomes, Resources and Evaluation once in every semester in a structured format floated by dean academics office.
- Parent Teacher Association (PTA) to develop the potential of parents and to strengthen their relationship with their children through planning and conducting a variety of developmental and recreational activities.
- Online Feedback is collected from all the students once at the end of the semester using well designed questionnaire. Informal feedback will be collected in parallel from selected student representatives within 4-5 weeks of commencement of the semester by the Office of Dean Academics.
- HODs have to submit monthly /semester / Academic Year Feedback reports with necessary comments and proofs to Dean Academics office duly signed by concerned Principal/Director.

## CHAPTER 11

### PROGRAMME STRUCTURE

		Koneru Lakshn	naiah Education	Foundatio	n							
		KL Co	llege of Pharma	су								
		M. Pharmacy 2023-24	Admitted Batch	n Course St	tructure	1	1		1			
SI No	CourseCode	Course Title	Name	Catego ry	Mode (R/A/P)	L	т	Ρ	s	Cr	СН	Pre- requisite
1.	22PY5101	Modern Pharmaceutical Analytical Techniques	MPAT	PCC	R	4	0	0	0	4	4	Nil
2.	22PY5102	Drug Delivery Systems	DDS	PCC	R	4	0	0	0	4	4	Nil
3.	22PY5103	0	4	4	Nil							
4.	22PY5104	Regulatory Affairs	RA	PCC	R	4	0	0	0	4	4	Nil
5.	22PY5105	Pharmaceutics Practical I	PP I	PCC	R	0	0	12	0	6	12	Nil
6.	22PY5107	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	MOL. P	PCC	R	4	0	0	0	4	4	DDS
7.	22PY5108	Advanced Biopharmaceutics & Pharmacokinetics	АВРРК	PCC	R	4	0	0	0	4	4	Nil
8.	22PY5109	Computer Aided Drug Delivery System	CADDS	PCC	R	4	0	0	0	4	4	Nil
9.	22PY5110	Cosmetic and Cosmeceuticals	CC	PCC	R	4	0	0	0	4	4	Nil
10.	22PY5111	Pharmaceutics Practical II	PP II	PCC	R	0	0	12	0	6	12	Nil
11.	22PY5113	Research Methodology and Biostatistics	RMB	PCC	R	4	0	0	0	4	4	Nil
		Total Credits (Professional Con	re Courses)		•		-	-		48		

12.	22PY5106		S/A	SDC			0	0	4	8	NII
13.	22PY5112	Seminar/Assignment	S/A	SDC		) (	8	0	4	8	NII
14.	22PY5114	Journal club	JC	SDC	(	) (	2	0	1	2	Nil
15.	22PY5115	Discussion / Presentation (Proposal Presentation)	D/P	SDC		0 0	4	0	2	4	Nil
16.	22PY5117	Journal Club	JC	SDC	(	) (	2	0	1	2	Nil
17.	22PY5119	Discussion/Final Presentation	D/P	SDC	(	) (	6	0	3	6	Nil
18.	22PY5120	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	COA	SDC		) (	8	0	4	8	Nil
		Total Credits (Skill Developme	ent Courses)						19		
19.	22PY5116	Research Work	RW	PRI	(	) (	28	0	14	28	Nil
20.	22PY5118	Research Work	RW	PRI		) (	33	0	16	33	Nil
		Total Credits (Project V	Vork)						30		
		Grand Total							97		

## CHAPTER 12

## ARTICULATION MATRIX

## Program Articulation Matrix

S. No.	Course	Course Name	Category	1	т	Р	S	Cr			P	os			PS	Os
	Code		catego: y	_		-		0.	1	2	3	4	5	6	1	2
1	22PY5101	Modern Pharmaceutical Analytical Techniques	PCC	4	0	0	0	4	3	2						
2	22PY5102	Drug Delivery System	PCC	4	0	0	0	4		3					3	
3	22PY5103	Modern Pharmaceutics	PCC	4	0	0	0	4	2	2						
4	22PY5104	Regulatory Affair	PCC	4	0	0	0	4					2	3		
5	22PY5105	Pharmaceutics Practical I	PCC	0	0	12	0	6			3				3	2
6	22PY5106	Seminar/Assignment	skill	0	0	8	0	4						2		
7	22PY5107	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	PCC	4	0	0	0	4		2	3					
8	22PY5108	Advanced Biopharmaceutics & Pharmacokinetics	PCC	4	0	0	0	4		3					2	
9	22PY5109	Computer Aided Drug Delivery System	PCC	4	0	0	0	4	3			3				
10	22PY5110	Cosmetic and Cosmeceuticals	PCC	4	0	0	0	4		2						
11	22PY5111	Pharmaceutics Practical II	PCC	0	0	12	0	6		3				3		
12	22PY5112	Seminar/Assignment	skill	0	0	8	0	4						2		
13	22PY5113	Research Methodology and Biostatistics	PCC	4	0	0	0	4				2	3			
14	22PY5114	Journal club	skill	0	0	2	0	1					2	2		
15	22PY5115	Discussion / Presentation (Proposal Presentation)	skill	0	0	4	0	2		2						
16	22PY5116	Research Work	skill	0	0	28	0	14		2	2					3
17	22PY5117	Journal Club	skill	0	0	2	0	1					2	2		
18	22PY5118	Research Work	skill	0	0	33	0	16		2	2					3
19	22PY5119	Discussion/Final Presentation	skill	0	0	6	0	3		2						3
20	220/5120	Co-curricular Activities (Attending Conference, Scientific		0		0		4			2			2		
	22815120	Presentations and Other Scholarly Activities)	skill	0	0	ð	0	4			2					
		Total		72	0	197	0	97		3       3       1       2         3       3       1       2         2       3       1       1       1         2       1       3       1       1       1         3       1       1       3       1       1         3       1       1       3       1       1         3       1       1       1       3       1         3       1       1       1       3       1         4       1       2       3       1       1         5       1       2       3       1       1         1       1       2       3       1       1         2       1       2       3       1       1         2       1       1       1       1       1         2       2       1       1       1       1       1         2       2       1       1       1       1       1       1         2       1       1       1       1       1       1       1         2       1       1       1       1						

## Course Articulation Matrix

							Program	Outcomes			PS	0
S.N O	Cours e Code	Course Title	Course Outcom es (COs)	Course Description	<b>PO</b> 1	<b>PO</b> 2	РО 3	<b>PO</b> 4	<b>PO</b> 5	PO 6	PSO 1	PSO 2
			CO1	Discuss the fundamental principles and applications of UV-visible, IR, flame emission, atomic absorption spectroscopy and spectroflourimetry	3	2						
			CO2	Understand the principles and applications of NMR spectroscopy in determination of structure of typical organic chemical compounds	3	2						
1	22PY5101	Modern Pharmaceutical	CO3	Appraise the role of MS spectrometry in elucidation of the structure of typical organic chemical compounds using	3	2						
		Analytical Techniques	CO4	Document the principles and applications of chromatographic, and electrophoretic separation techniques	3	2						
			CO5	Describe the concepts in electrophoresis and radio-immuno assays	2	2						
			CO6	Describe the principles and applications of X-Ray crystallography	2	2						

			CO1	Understand the concepts involved in SR and CR drug delivery systems		3			3	
			CO2	Identify suitable drugs and polymers for specific controlled drug delivery systems and discuss modern strategies		3			3	
			CO3	Understand various approaches for rate controlled and ocular drug delivery systems		3			3	
2	22PY5102	Drug Delivery Systems	CO4	Understand the formulation concepts involved in development of GRDDS, buccal and transdermal DDS		3			3	
			CO5	Illustrate the evaluation of buccal and transdermal DDs		2			3	
			CO6	Illustrate the need and application of novel strategies in delivery of biosimilars like proteins, peptides and vaccines		3			3	
			CO1	Discuss various preformulation concepts in dosage formdevelopment	2					
			CO2	Develop new dosage forms by applying the principles of optimization		2				
3	22PY5103	Modern Pharmaceutics	CO3	Design validation protocol for solid and liquid dosage forms		2				
			CO4	Apply the cGMP and Industrial management principles in dosage form development		2				
			CO5	Understand the process of compaction and compression in soliddosage form development	2					

			CO6	Understand the study of consolidation parameter	2				
			CO1	Understand the concepts of innovator and generic drugs in drug development process			2		
			CO2	Understand Regulatory requirements for new drug application approval in pharmaceuticals				3	
			CO3	Understand ICH guidelines for filing and approval process of drug products in different countries			2		
4	22PY5104	Regulatory Affairs	CO4	Analyse the post approval regulatory requirements for products and submission of global documents in Common Technical Document/ eCTD formats				3	
			CO5	Illustrate the regulatory procedures involved in non- clinical andclinical drug development				2	
			CO6	Apply the principles of regulatory affairs in drug developmentprocess, filing and approval, non-clinical and clinical drug development in global scenario				2	
5	22PY5105	Pharmaceutics Practical I	CO1	Analyse the Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, Demonstrate the experiments using HPLC and Gas Chromatography		3			2

							1		
				Estimate Pharmacopoeial substances by Fluorimetry and Flame Photometry					
			CO2	Formulate and evaluate the different marketed formulations Analyze the precompression parameters and understand the influence of excipients on product performance Construct the release kinetic plots through model dependent and independent methods		3			2
			CO1	Select topic from the course content for deep learning towards seminar presentation				2	
6 22			CO2	Develop advanced content and present it as seminar				2	
	22PY5106	Seminar/Assignment	CO3	Select topic from the course content for deep learning towards assignment preparation				2	
			CO4	Develop advanced content and present it as assignment				2	
			CO1	Understand the concepts involved in drug targeting systems	2				
			CO2	Understand the preparation and evaluation of targeting methods	2				
7	22PY5107	Molecular Pharmaceutics (Nano Tech and Targeted	CO3	Design and develop various delivery systems for a specific drugtargets	3				
22PY51		DDS)	CO4	Understand the preparation and evaluation of intra nasal formulations	3				
			CO5	Understand the nucleic acid- based therapeutic drug delivery system	3				

			CO6	Applications of the potential target diseases for gene therapy		3				
			CO1	Understand the mechanisms and factors affecting ADME processes through GIT		2			2	
			CO2	Discuss several biopharmaceutic considerations, BCS, IVIVC and permeability in drug product design and in vitro drug product performance		3			2	
			CO3	Understand the impact of drug interactions on drug action		3			2	
8	22PY5108	Advanced Biopharmaceutics & Pharmacokinetics	CO4	Explain the protocol for bioavailability/bioequivalence studies and their role in generic product development		3			2	
			CO5	Illustrate the assessment of pharmacokinetic parameters assuming different models		3			2	
			CO6	Illustrate the application of pharmacokinetic principles indevelopment of drug products and biosimilars		3			2	
			CO1	Explain the history of computers in pharmaceutical research and development	3					
9	22PY5109	Computer Aided Drug Delivery Systems	CO2	Explain computational modeling of drug disposition	3		3			
7			CO3	Apply the approaches of optimization techniques in pharmaceutical formulation	3		3			

			CO4	Understand the importance of computers in biopharmaceutical characterization	3			3			
			CO5	Understand the role of computer simulations in PK-PD and clinical data management	3			3			
			CO6	Illustrate the application of AI, robotics and CFD in pharmacy field	3			3			
			CO1	To know the Regulatory provisions related to the import, manufacture and sale of cosmetics		2				1	
10			CO2	Understand the diverse skin problems and how to overcome through skin preparations		2				1	
		Cosmetic and	CO3	Formulation and evaluation of a variety of cosmetic products		2				1	
10	22PY5110	Cosmeceuticals	CO4	Understanding the key ingredients and basic science to develop cosmetics and Cosmeceuticals		2				1	
			CO5	To gain the knowledge of the various technologies involved in cosmetics manufacture		2				1	
			CO6	To understand the Design of cosmeceuticals and herbal formulations		2				1	
11	22PY5111	Pharmaceutics Practical II	CO1	Demonstrate the practical skills in development and evaluation of novel systems. Demonstrate the BA studies, PK-PD analysis, and IVIVC			3				

				Apply computational tools in product development and optimization					
			CO2	Understand the concept and application of PK-PD simulation models. Understand the clinical data collection and population modeling Demonstrate the formulation and evaluation of cosmeceuticals	2				
			CO1	Select topic from the course content for deep learning towardsseminar presentation				2	
			CO2	Develop advanced content and present it as seminar				2	
12 <b>22PY5</b>	22PY5112	Seminar/Assignment	CO3	Select topic from the course content for deep learning towards assignment preparation				2	
			CO4	Develop advanced content and present it as assignment				2	
			CO1	Understand the basic principles of research methodology and its role in pharmaceutical aspect		1	3		
			CO2	Understand the basic concepts of biostatistics		1	3		
			CO3	Illustrate the importance of biostatistics in research		2	3		
13	22PY5113	Research Methodology and Biostatistics*	CO4	Develop research proposal following the principles of medical research			3		
			CO5	Understand and apply the guidelines of CPCSEA in preclinical experimentation			3		
			CO6	Understand the principles of Declaration of Helsinki			3		

			CO1	Identify the research problem	2				
			CO2	iscuss research problem with team, peers and guide for solution	2				
14	22PY5114	Journal club	CO3	Develop a protocol report on the critically appraised research problem with aim and objectives	2				
			CO4	Analyse and present the critically appraised research problem in appropriate form and discuss the plan of work	2				
			CO1	Conduct literature review and come to conclusions on selection of drugs/excipients/methods/technique s	2				2
		Discussion /	CO2	Develop a research protocol or plan of work	2				3
15	22PY5115	Presentation(Proposal Presentation)	CO3	Conduct research experiments to meet the aim and objectives of proposed research work	2	2			3
			CO4	Evaluate the findings and plan alterations or new methodologies or procedures for further improvement	2	2			3
			CO1	Conduct literature review and come to conclusions on selection of drugs/excipients/methods/technique s	2				2
16	22PY5116	Research Work	CO2	Develop a research protocol or plan of work	2				3
10			CO3	Conduct research experiments to meet the aim and objectives of proposed research work	2	2			3

			CO4	Evaluate the findings and plan alterations or new methodologies or procedures for further improvement	2	2			3
			CO5	Document the findings of conducted experiments	2				2
			CO6	Interpret the results obtained and plan further activities	2				2
			CO1	Select a research paper published in reputed journal by using search engines and databases			2	2	
17	22PY5117	Journal Club	CO2	Critically appraise the published research work			2	2	
			CO3	Develop a report			2	2	
			CO4	Present the critical observations and discuss			2	2	
			CO1	Review the latest literature in selected area of work	2				2
	22PY5118		CO2	Conduct research experiments to meet the aim and objectives of proposed research work	2	3			3
18		Research Work	CO3	Evaluate the findings and plan alterations or new methodologies or procedures for further improvement	2	3			3
			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
			CO6	Draft the chapters for thesis	2				2
			CO1	Interpret the observations and results	2				3
19	22PY5119	Discussion/Final	CO2	Develop the presentation in an organized manner	2				2
	19 <b>22PY5119</b>	Presentation	CO3	Explain the followed methods and results	2				2

			CO4	Defend the questions from experts and neers	2				3
	22BV5120	Co-curricular Activities (Attending	CO1	Participate in external scientific/technical programs like conferences /seminars/symposia		2		2	
20	221 13120	Conference, Scientific Presentations and Other Scholarly Activities)	CO2	Present their technical or research work		2		2	
			CO3	Perform scientific paper writing and critical thinking		2		2	
			CO4	Perform team management and networking		2		2	

## CHAPTER 13

#### SYLLABUS

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPAT)

	22613101	INIODE	n	LIPS	4-0-0-0	PRE-REQU	JISHE	INII
Outcom	es							
CO Des	CO Description							PO Mapping
Investig organic atomic	Investigation, characterization and quantification of typical organic chemical compounds using UV-visible, IR, flame emission atomic absorption spectroscopy and spectroflourimetry						2	1, 2
Investig chemic	ation and dete al compounds ι	rmination Ising NMF	of tl ≀ spe	he struct ctrosco	ture of typi ວy	cal organic	3	1, 2
Investig chemic	ation and dete al compounds ι	rmination Ising MS s	of tl spect	he struct crometry	ture of typi /	cal organic	3	1, 2
Isolatio chemic	n, purification al compounds u	and qu Ising chro	uanti mate	ification ography	of typica techniques	al organic s	2	1, 2
Concep	ts in electropho	presis and	radi	o-immu	no assays		2	1, 2
Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods					of typical	3	1, 2	
S								
ie 1 Ov wi Ap IR Ins Fla Ins Qu sp	th UV-Visible plications of UV spectroscopy: strumentation of ecting vibration me emission s strumentation, f ectroflourimetion enchers, In ectrophotometic	spectroso / Visible s Theory, of Dispers nal freque <b>pectroso</b> Interferer ry: Theor strument er.	ive a ncies opy nces y o atior	dection, , Choice roscopy des of and Four s and App and App f Fluore n an	Molecular Molecular rier - Trans oplications <b>omic absor</b> lications. escence, Fa	vibrations, vibrations, form IR Spectro of IR spectro <b>ption spect</b> actors affect cations	Sample Sample ectromete oscopy croscopy: cting fluc of flu	ffect and handling, er, Factors Principle, prescence, orescence
<ul> <li>Module 2</li> <li>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.</li> <li>Module 3</li> <li>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</li> </ul>					Principle, Signals in Spin-Spin outline of ctroscopy, nd MALDI, mentation			
	Outcome         CO Des         Investig         organic         atomic         Investig         chemic         Investig         chemic         Isolatio         chemic         Isolatio         chemic         Investig         chemic         Isolatio         chemic         Investig         chemic         Investig         chemic         Soncep         Investig         chemic         Soncep         Investig         chemic         Soncep         Ins         aff         Fla         Ins         aff         Fla         Ins         op         le 2         Ma         Dif         AP         Dif         AP	Outcomes         CO Description         Investigation, charaction         organic chemical compation specification and determical compounds of the chemical compounds of	Outcomes           CO Description           Investigation, characterization organic chemical compounds us atomic absorption spectroscopy           Investigation and determination chemical compounds using NMF           Investigation and determination chemical compounds using MS s           Isolation, purification and que chemical compounds using chro           Concepts in electrophoresis and           Investigation and determination chemical compounds using X-Ra           S           le 1         UV-Visible spectroscopy: In with UV-Visible spectroscopy: In with UV-Visible spectroscopy: In mith UV-Visible spectroscopy: In spectroscopy: Theory, Instrumentation of Dispers affecting vibrational freque Flame emission spectroscopy Instrumentation, Interferent Spectroflourimetry: Theor Quenchers, Instrument spectrophotometer.           le 2         NMR spectroscopy: Quar Instrumentation, Solvent re various compounds, Chemi coupling, Coupling constant principles of FT-NMR and 1           le 3         Mass Spectroscopy: Princi Different types of ionization APCI, ESI, APPI Analyzers o	Outcomes           CO Description           Investigation, characterization and organic chemical compounds using U atomic absorption spectroscopy and           Investigation and determination of the chemical compounds using NMR spect           Investigation and determination of the chemical compounds using MS spect           Isolation, purification and quantic chemical compounds using Chromatic           Concepts in electrophoresis and radii           Investigation and determination of chemical compounds using X-Ray Different in UV-Visible spectroscopy: Introcompounds using X-Ray Different spectroscopy: Theory, Mo Instrumentation of Dispersive a affecting vibrational frequencies           Flame emission spectroscopy Instrumentation, Interferences           Spectroflourimetry: Theory or Quenchers, Instrumentation spectrophotometer.           Ie 2         NMR spectroscopy: Quantum Instrumentation, Solvent requir various compounds, Chemical s coupling, Coupling constant, Nu principles of FT-NMR and 13C N           Ie 3         Mass Spectroscopy: Principle, Different types of ionization like APCI, ESI, APPI Analyzers of Qu	Outcomes           CO Description           Investigation, characterization and quan organic chemical compounds using UV-visibl atomic absorption spectroscopy and spectro           Investigation and determination of the struct chemical compounds using NMR spectroscop           Investigation and determination of the struct chemical compounds using MS spectrometry           Isolation, purification and quantification chemical compounds using chromatography           Concepts in electrophoresis and radio-immu           Investigation and determination of the chemical compounds using X-Ray Diffraction           s           le 1         UV-Visible spectroscopy: Introduction, with UV-Visible spectroscopy. Choice Applications of UV Visible spectroscopy. IR spectroscopy: Theory, Modes of Instrumentation of Dispersive and Four affecting vibrational frequencies and App Spectroflourimetry: Theory of Fluore Quenchers, Instrumentation and spectrophotometer.           le 2         NMR spectroscopy: Quantum numbi Instrumentation, Solvent requirement in various compounds, Chemical shift, Fac coupling, Coupling constant, Nuclear ma principles of FT-NMR and 13C NMR. App Different types of ionization like electro APCI, ESI, APPI Analyzers of Quadrupole	Outcomes         CO Description         Investigation, characterization and quantification organic chemical compounds using UV-visible, IR, flame atomic absorption spectroscopy and spectroflourimetry         Investigation and determination of the structure of typi chemical compounds using NMR spectroscopy         Investigation and determination of the structure of typi chemical compounds using MS spectrometry         Isolation, purification and quantification of typic chemical compounds using chromatography technique:         Concepts in electrophoresis and radio-immuno assays         Investigation and determination of the structure chemical compounds using X-Ray Diffraction methods         s         le 1       UV-Visible spectroscopy: Introduction, Theory, Law with UV-Visible spectroscopy.         IR spectroscopy: Theory, Modes of Molecular Instrumentation of Dispersive and Fourier - Trans affecting vibrational frequencies and Applications.         Spectroflourimetry: Theory of Fluorescence, Flue Quenchers, Instrumentation and Applications.         Spectroflourimetry: Theory of Fluorescence, Flue Quenchers, Instrumentation and Applications.         Spectroflourimetry: Theory of Fluorescence, Flue Quenchers, Instrumentation and Applications.         Spectroflourimetry: Theory of Fluorescence, Flue Quenchers, Instrumentation and Applications.         Spectroflourimetry: Theory of Fluorescence, Flue Quenchers, Instrumentation and Applications.         Spectroflourimetry: Theory of Fluorescence, Flue Quenchers, Instrumentation and Applications. <tr< td=""><td>Outcomes           CO Description           Investigation, characterization and quantification of typical organic chemical compounds using UV-visible, IR, flame emission, atomic absorption spectroscopy and spectroflourimetry           Investigation and determination of the structure of typical organic chemical compounds using NMR spectroscopy           Investigation and determination of the structure of typical organic chemical compounds using MS spectrometry           Isolation, purification and quantification of typical organic chemical compounds using chromatography techniques           Concepts in electrophoresis and radio-immuno assays           Investigation and determination of the structure of typical organic chemical compounds using X-Ray Diffraction methods           s           le 1         UV-Visible spectroscopy: Introduction, Theory, Laws, Instrument with UV-Visible spectroscopy, Choice of solvents and s Applications of UV visible spectroscopy.           IR spectroscopy: Theory, Modes of Molecular vibrations, Instrumentation of Dispersive and Fourier - Transform IR Spectroscopy ibrational frequencies and Applications of IR spectro Flame emission spectroscopy and Atomic absorption spect Instrumentation, Interferences and Applications.           Spectroflourimetry: Theory of Fluorescence, Factors affect Quenchers, Instrumentation and Applications of NMR spectroscopy: Quantum numbers and their role i Instrumentation, Solvent requirement in NMR, Relaxation procivarious compounds, Chemical shift, Factors influencing chemical coupling, Coupling constant, Nuclear magnetic double resonal principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy: Principle, Theory, Instrumentation of M</td><td>Outcomes         BTL           Investigation, characterization and quantification of typical organic chemical compounds using UV-visible, IR, flame emission, atomic absorption spectroscopy and spectroflourimetry         2           Investigation and determination of the structure of typical organic chemical compounds using NMR spectroscopy         3           Investigation and determination of the structure of typical organic chemical compounds using MS spectrometry         3           Investigation and determination of the structure of typical organic chemical compounds using chromatography techniques         2           Concepts in electrophoresis and radio-immuno assays         2           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation of UV-Visible spectroscopy.         3           IR spectroscopy: Theory, Modes of Molecular vibrations, Sample Instrumentation of Dispersive and Fourier - Transform IR Sp</td></tr<>	Outcomes           CO Description           Investigation, characterization and quantification of typical organic chemical compounds using UV-visible, IR, flame emission, atomic absorption spectroscopy and spectroflourimetry           Investigation and determination of the structure of typical organic chemical compounds using NMR spectroscopy           Investigation and determination of the structure of typical organic chemical compounds using MS spectrometry           Isolation, purification and quantification of typical organic chemical compounds using chromatography techniques           Concepts in electrophoresis and radio-immuno assays           Investigation and determination of the structure of typical organic chemical compounds using X-Ray Diffraction methods           s           le 1         UV-Visible spectroscopy: Introduction, Theory, Laws, Instrument with UV-Visible spectroscopy, Choice of solvents and s Applications of UV visible spectroscopy.           IR spectroscopy: Theory, Modes of Molecular vibrations, Instrumentation of Dispersive and Fourier - Transform IR Spectroscopy ibrational frequencies and Applications of IR spectro Flame emission spectroscopy and Atomic absorption spect Instrumentation, Interferences and Applications.           Spectroflourimetry: Theory of Fluorescence, Factors affect Quenchers, Instrumentation and Applications of NMR spectroscopy: Quantum numbers and their role i Instrumentation, Solvent requirement in NMR, Relaxation procivarious compounds, Chemical shift, Factors influencing chemical coupling, Coupling constant, Nuclear magnetic double resonal principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy: Principle, Theory, Instrumentation of M	Outcomes         BTL           Investigation, characterization and quantification of typical organic chemical compounds using UV-visible, IR, flame emission, atomic absorption spectroscopy and spectroflourimetry         2           Investigation and determination of the structure of typical organic chemical compounds using NMR spectroscopy         3           Investigation and determination of the structure of typical organic chemical compounds using MS spectrometry         3           Investigation and determination of the structure of typical organic chemical compounds using chromatography techniques         2           Concepts in electrophoresis and radio-immuno assays         2           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation and determination of the structure of typical chemical compounds using X-Ray Diffraction methods         3           s         3           Investigation of UV-Visible spectroscopy.         3           IR spectroscopy: Theory, Modes of Molecular vibrations, Sample Instrumentation of Dispersive and Fourier - Transform IR Sp

spectroscopy.Module 4Chromatography: Principle, apparatus, instrumentation, chromatographic<br/>parameters, factors affecting resolution and applications of the following: a) Paper<br/>chromatography b) Thin Layer chromatography c) Ion exchange chromatography d)<br/>Column chromatography e) Gas chromatography f) High Performance Liquid<br/>chromatography g) Affinity chromatography

Module 5	<b>Electrophoresis</b> : 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.
Module 6	<b>X ray Crystallography</b> : 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.

SI No	Title	Author(s)	Publisher	Year
1	Principles of Instrumental Analysis	Doglas A	Eastern press, Bangalore	1998.
		James Holler,		
		Timothy A. Nieman		
2	Quantitative Analysis of	P D Sethi	CBS Publishers, New Delhi,	1997
	formulation		,	
3	Spectroscopy by Silverstein	John & Wiley & Sons. Inc.,	Wiley publications	2014
4	Instrumental Analysis	Willard and Merritt	EWP, East West Press Ltd., Delhi/Madras	2009
5	Organic spectroscopy.	Y.R. Sharma	Chand Publishers, Delhi	2013

Global Certifications:

Mapped Global Certifications:

1110						
		Certifica				
SI		tion	Proct	Format	Exam	URL of the
Ν		Provide	ored	of the	Provi	Certification
0	Title	r	(Y/N)	Exam	der	
1	Spectroscopic Techniques For Pharmaceutical And Biopharmaceutical Industries	IIT Delhi	Yes	Online	NPTE L Sway am	https://onlinecourse s.nptel.ac.in/noc23_c y44/preview

Tools used in Practical / Skill:

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1	Not applicable	Not applicable	Not applicable

Evaluation Components:

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

## DRUG DELIVERY SYSTEMS (DDS)

COURSE CODE	OURSE CODE 22PY5102		R	LTPS	4-0-0-0	PRE-REQUISITE	Nil

urse O	utcomes						
CO#	CO Description	CO Description					
CO1	Understand the concepts involved in SR and CR drug delivery systems					2	
CO2	Identify suitable drugs and polymers for specific controlled drug delivery systems and discuss modern strategies				2	2	
CO3	Understand various approaches for rate controlled and ocular drug delivery systems				2	2	
CO4	Understand the formulation concepts involved in development of GRDDS, buccal and transdermal DDS					2	
CO5	Illustrate the evaluation of buccal and transdermal DDs					2	
CO6	Illustrate the need and applicatior of biosimilars like proteins, peptide	i of novel stra	ategies in de es	elivery	3	2	

#### Syllabus

Module	Contents
Module-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 for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy
Module-2	<b>Rate Controlled Drug Delivery Systems:</b> 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. <b>Ocular</b> <b>Drug Delivery Systems:</b> Barriers of drug permeation, Methods to overcome barriers.
Module-3	<b>Gastro-Retentive Drug Delivery Systems:</b> 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.
Module-4	<b>Transdermal Drug Delivery Systems:</b> Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. <b>Protein and Peptide Delivery:</b> Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

S. No	Title	Author(s)	Publisher	Year
1	Novel Drug Delivery Systems	Y W. Chien	Marcel Dekker, Inc.	2021
2	Encyclopedia of Controlled Delivery	Edith Mathiowitz	John Wiley and Sons,	2018
3	Controlled Drug Delivery - concepts and advances	S.P. Vyas and R.K. Khar	Vallabh Prakashan, New Delhi.	2020
4	Controlled and Novel Drug Delivery	N.K. Jain	CBS Publishers	2022
5	Controlled Drug Delivery Systems	Robinson, J. R., Lee V. H. L	Marcel Dekker, Inc.,	2017

Global Certifications: NA

Mapp	Mapped Global Certifications:								
SI	Titl	Certification	Proctored	Format of the	Exam	URL of the			
No	е	Provider	(Y/N)	Exam	Provider	Certification			
1									

Tools used in Practical / Skill: NA

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1			

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

# MODERN PHARMACEUTICS (MP) COURSE CODE 22PY5103 MODE R LTPS 4-0-0-0 PRE-REQUISITE Nil

COURSE CODE 22PY5103 MODE R LTPS 4-0-0-0 PRE-R						PRE-REQU	JISITE	Nil		
Course	Course Outcomes									
CO#	CO Descri	CO Description BTL PO Mapping								
CO1	Discuss Developm	various pref ient.	ormulatio	on	concept	s in dosa	age form	2		2
CO2	Develop optimizat	new dosage ion.	forms	by	applyin	g the prir	ciples of	3		2
СОЗ	Design validation protocol for solid and liquid dosage forms.						rms.	2		2
CO4	Apply the cGMP and Industrial management principles in dosage form development.					in dosage	3		2	
CO5	Understai in solid do	nd the proo osage form de	cess of velopme	cor nt.	npactior	n and coi	mpression	2		2
CO6	Understa	nd the study o	of consoli	datio	on paran	neter		2		2

## Syllabus

Module 1	<b>Preformulation Concepts</b> – 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.
Module 2	<b>Optimization techniques</b> - in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Factorial designs and application in formulation.
Module 3	<b>Validation</b> : 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.
Module 4	<b>cGMP &amp; Industrial Management</b> : 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.
Module 5	<b>Compression and compaction</b> : Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles

Module 6	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.

SI No	Title	Author(s)	Publisher	Year
1	Theory and Practice of Industrial	by Lachmann and		
	Pharmacy	Libermann	Decker series	2010
2				
	Pharmaceutical dosage forms	ALTUON	Decker series	2008
3				
	Modern Pharmaceutics	Banker and series	Decker series	2009
4		by Lachmann and		
	Advances in Pharmaceutical Sciences	Libermann	Decker series	2002
5	Pharmaceutical Dosage forms:	by Lachmann and		
	Disperse systems	Libermann	Decker series	2001

#### **Global Certifications:**

Мар	Mapped Global Certifications:					
SI		Certificat ion	Proctored	Format of the	Exam	URL of the Certification
No	Title	Provider	(Y/N)	Exam	Provider	certification
1	Good manufactu ring practice	yes	Y	LMS Quiz	USAID	https://www.usai d.gov/

Global Certifications:

Мар	Mapped Global Certifications:						
SI		Certifica tion	Procto red	Format of the		URL of the	
No	Title	Provider	(Y/N)	Exam	Exam Provider	Certification	
1	Modern pharmace utics	USAID	Y	Online	Good manufacturing practices	https://www.us aid.gov/	
<b>T</b> I .							

Tools used in Practical / Skill:

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1	NA	NA	NA

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

## REGULATORY AFFAIR (RA)

COURS	COURSE CODE 22PY5104 MODE R LTPS 4-0-0-0 PRE-REC							IISITE	Nil
Course	Course Outcomes								
CO#	CO Description BTL PO Mapping								
CO1	Understand the concepts of innovator and generic drugs in drug21,2development process1								
CO2	O2 Understand Regulatory requirements for new drug application 2 1,2 approval in pharmaceuticals						1,2		
CO3	Understand ICH guidelines for filing and approval process of drug products in different countries						ess of drug	2	1,2
CO4	Illustrate the post approval regulatory requirements for products and submission of global documents in Common Technica Document/ eCTD formats						r products Technical	3	1,2
CO5	Illustrate the regulatory procedures involved in non-clinical and clinical drug development						linical and	3	1,2
CO6	Apply the principles of regulatory affairs in drug developmen process, filing and approval, non-clinical and clinical dru development in global scenario						velopment nical drug	3	1,2

## Syllabus

Module 1	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.
Module 2	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.
Module 3	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).
Module 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.
	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:

SI No	Title	Author(s)	Publisher Year
1	Generic Drug Product Development,	Leon Shargel and	CRC Press 2005
	Solid Oral Dosage forms	IsaderKaufer,	
2	The Pharmaceutical Regulatory	Ira R. Berry and	CRC Press 2008
	Process	Robert P. Martin	

3	FDA R Prescri and Bio	egulatory ption Dr plogics	y Affairs: A rugs, Medica	Guide for I Devices,	Douglas J. Pisano	CRC Press	2008
4	New Acceler	Drug rating Glo	Approval obal Registrat	Process: tions	Richard A Guarino	CRC Press	2004
Clobal (							

Global Certifications:

Ma	Mapped Global Certifications:								
SI			Proctor			LIBL of the			
Ν		Certification	ed	Format of		Cortification			
0	Title	Provider	(Y/N)	the Exam	Exam Provider	Certification			
		Regulatory affairs			Regulatory affairs				
1	Regulato	professional	v	Onling	professional	RAPS - Online			
T	ry affairs	society	ř	Onnie	society	U Certificate			
						LP			

#### Tools used in Practical / Skill:

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1	NA	NA	NA

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

## PHARMACEUTICS PRACTICAL I (PP-I)

COURSE CODE	22PY5105	MODE	R	LTPS	0-0-	PRE-	Nil
					12-0	REQUISITE	

Course O	utcomes		
CO#	CO Description	BTL	PO
			Mapping
CO1	Analyse the Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, Demonstrate the experiments using HPLC and Gas Chromatography Estimate Pharmacopoeial substances by Fluorimetry and Flame Photometry	4	3
CO2	Formulate and evaluate the different marketed formulations Analyze the precompression parameters and understand the influence of excipients on product performance Construct the release kinetic plots through model dependent and independent methods	4	3

Syllabus

Module	Contents
Module-I	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
Module-II	1. Formulation and evaluation of sustained release matrix tablets
	2. Formulation and evaluation osmotically controlled DDS
	3. Preparation and evaluation of Floating DDS- hydro dynamically balanced
	DDS
	<ol><li>Formulation and evaluation of Muco adhesive tablets.</li></ol>
	5. Formulation and evaluation of trans dermal patches.
	<ol><li>To carry out preformulation studies of tablets.</li></ol>
	7. To study the effect of compressional force on tablets disintegration time.
	8. To study Micromeritic properties of powders and granulation.
	9. To study the effect of particle size on dissolution of a tablet.
	10. To study the effect of binders on dissolution of a tablet.
	11. To plot Heckal plot, Higuchi and peppas plot and determine similarity
	factors

## Reference Books:

S. No	Title	Author(s)	Publisher	Year
1	Modern Pharmaceutics	Gillbert and S. Banker.	CRC Press Inc	2002
2	Pharmaceutical Sciences.	Remington	Elsevier	2021
3	Advances in Pharmaceutical Sciences	H.S. Bean & A.H. Beckett.	Academic Press Inc.	1997
4	Bentley's Textbook of Pharmaceutics	Rawlins.	Elsevier	2010

### Global Certifications: NA

Марр	Mapped Global Certifications:							
SI	Titl	Certification	Proctored	Format of the	Exam	URL of the		
No	e	Provider	(Y/N)	Exam	Provider	Certification		
1								
2								

#### Tools used in Practical / Skill: NA

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1			

Evaluation	Component	Weightage	Total
In-Sem	Attendance	6.65	
Formative	Lab continuous evaluation	6.65	13.3
In-Sem	Semester In lab exam-I	10	
Summative	Semester In lab exam-II	10	20
End-Sem	End Semester Exam		
Summative		66.7	66.7
		Grand Total	100

## MOLECULAR PHARMACEUTICS (MP)

						· · ·	
COURSE CODE	22PY5107	MODE	R	LTPS	4-0-0-0	PRE-REQUISITE	DDS

CO#	CO Description	BTL	PO Mapping
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 drug target	3	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	3	2

#### Syllabus

Module	Contents
Module-1	<b>Targeted Drug Delivery Systems:</b> Concepts, Events and biological process involved in drug targeting. Tumour targeting and Brain specific delivery.
	<b>Targeting Methods</b> : introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation
Module-2	<b>Micro Capsules / Micro Spheres</b> : Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Noisome, Aquasomes, Phytosomes, Electrosomes.
Module-3	<b>Pulmonary Drug Delivery Systems:</b> Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.
Module-4	<ul> <li>Nucleic acid based therapeutic delivery system: Gene therapy, introduction (exvivo &amp; in-vivo genetherapy).</li> <li>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.</li> </ul>

#### Reference Books:

S. No	Title	Author(s)	Publisher	Year
1	Novel Drug Delivery Systems	Y W. Chien	Marcel Dekker, Inc.	2021
2	Encyclopedia of Controlled Delivery	Edith Mathiowitz	John Wiley and Sons,	2018
3	Controlled Drug Delivery -concepts and advances	S.P. Vyas and R.K. Khar	Vallabh Prakashan, New Delhi.	2020
4	Controlled and Novel Drug Delivery	N.K. Jain	CBS Publishers	2022
5	Controlled Drug Delivery Systems	Robinson, J. R., Lee V. H. L	Marcel Dekker, Inc.,	2017

#### Global Certifications: NA

Мар	Mapped Global Certifications:						
SI	Titl	Certification	Proctored	Format of the	Exam	URL of the	
No	е	Provider	(Y/N)	Exam	Provider	Certification	
1							
2							

## Tools used in Practical / Skill: NA

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1			
2			

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

## ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS (ABPK)

 COURSE CODE
 22PY5108
 MODE
 Regular
 LTPS
 4-0-0-0
 PRE-REQUISITE
 Nil

 Course Outcomes

CO	CO Description	BTL	PO Mapping
CO-1	Understand the mechanisms and factors affecting ADME processes through GIT	2	2
CO-2	Discuss several biopharmaceutic considerations, BCS, IVIVC and permeability in drug product design and in vitro drug product performance	2	2
CO-3	Understand the impact of drug interactions on drug action	2	2
CO-4	Explain the protocol for bioavailability/bioequivalence studies and their role in generic product development	2	2
CO-5	Illustrate the assessment of pharmacokinetic parameters assuming different models	2	3
CO-6	Illustrate the application of pharmacokinetic principles in development of drug products and biosimilars	2	3

Syllabus

Module 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 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.
Module 2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product
	<b>Performance:</b> 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,
	dissolution, alternative methods of dissolution testing, meeting
	assolution requirements, problems of variable control in dissolution testing
	performance of drug products.
Module 3	Invitro-invivo 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.					
Module 4	Pharmacokinetics: Basic considerations pharmacokinetic models compartment					
Wodule +	modelling: one compartment model- IV bolus IV infusion extra-vascular Multi					
	compartment model woodel					
	compartment - model in brief, non-linear pharmacokinetics; cause of non-linearity					
	Michaelic Monton equation estimation of kmax and ymax					
	Drug Product Devformence in vive Piecweilebility and Piecewivelence Drug product					
	brug product performance, in vivo: bloavailability and bloequivalence. Drug product					
	performance, purpose of bloavailability studies, relative and absolute availability.					
	methods					
	for assessing bloavailability.					
Module 5	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.					
Module 6	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.					

SI No	Title	Author(s)	Publisher	Year
1	Biopharmaceutics and Clinical		Lea and	
	Pharmacokinetics	Milo Gibaldi	Febiger	1991
2		A. Treatise, D. M.	Vallab	
	Biopharmaceutics and	Brahmankar and	Prakashan,	
	Pharmacokinetics	Sunil B. Jaiswal	Pitampura	2002
3			Connecticut	
	Applied Biopharmaceutics and		Appleton	
	Pharmacokinetics	Shargel. Land	Century Crofts	1985
4	Biopharmaceutics and	Dr. Shobha Rani		
	Pharmacokinetics	R. Hiremath	Prism Book	2001
5	Pharmacokinetics by Milo Gibaldi	Marcel Dekker	Lea and	
	and D. Perrier	Inc	Febiger	1982

#### **Global Certifications:**

Мар	ped Global Ce	rtifications:				
SI		Certificat ion	Proctored	Format of the	Exam	URL of the
No	Title	Provider	(Y/N)	Exam	Provider	certification
1	Good manufactu ring practice	yes	Y	LMS Quiz	USAID	https://www.usai d.gov/

#### Tools used in Practical / Skill:

SI No	Tool Name	Parent Industry	Parent Industry		Open Source/ Commercial	
1	NA	NA	NA			
Evaluation C	omponents:	·				
Evaluation	Component		Weig	htage	Total	
	Attendance		8			
In-Sem	Question and Answers		2			
Formative					10	
In-Sem	Semester in Exam-I		7.5		15	
Summative	Semester in Exam-II		7.5			
End-Sem	End Semester Exam		75		75	
Summative						

## COMPUTER AIDED DRUG DELIVERY SYSTEM (CADDS)

COURSE CODE	22PY5109	MODE	R	LTPS	4-0-0-0	PRE-	Nil
						REQUISITE	

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

#### Syllabus

Module	Contents
Module-1	<ul> <li>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</li> <li>Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.</li> <li>Computational Modeling of Drug Disposition: Introduction, Modeling</li> </ul>
	Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT2, ASBT, OCT, OATP, BBB-Choline Transporter.
Module-2	<b>Computer-aided formulation development:</b> 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.
Module-3	<b>Computer-aided biopharmaceutical characterization</b> : Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and <i>in vitroin vivo</i> correlation, Biowaiver considerations.
Module-4	<b>Computer Simulations in Pharmacokinetics and Pharmacodynamics:</b> 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.

S. No	Title	Author(s)	Publisher	Year
1	Encyclopedia of Pharmaceutical Technology	James Swarbrick, James. G.Boylan,	Marcel Dekker Inc, New York,	2019
2	Computer Applications in Pharmaceutical Research and Development	Sean Ekins	John Wiley & Sons.	2017
3	Computer-Aided Applications in Pharmaceutical Technology	Jelena Djuris	Woodhead Publishing	2012

Global Certifications: NA

Марр	Mapped Global Certifications:							
SI	Titl	Certification	Proctored	Format of the	Exam	URL of the		
No	е	Provider	(Y/N)	Exam	Provider	Certification		
1								
2								

#### Tools used in Practical / Skill: NA

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1			
2			

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

#### COSMETIC AND COSMECEUTICALS (CC) T

COURS	SE CODE	22PY5110	MODE	R	LTPS	4-0-0-0	PRE-REQU	JISITE	Nil
Course	·								
CO#	CO Descri	ption						BTL	PO Mapping
CO1	To know manufact	the Regula ure and sale c	tory pro of cosmet	visio ics.	ns rela	ted to th	e import,	2	2
CO2	Understar through s	nd the divers kin preparatio	se skin p ons	orobl	ems an	d how to	overcome	2	2
CO3	To understand the formulation and evaluation of a variety of cosmetic products.						variety of	2	2
CO4	Understanding the key ingredients and basic science to develop cosmetics and Cosmeceuticals.						o develop	2	2
CO5 To gain the knowledge of the various technologies involved in cosmetics manufacture.							2	2	
CO6	To unde formulatio	rstand the ons.	Design	of	cosmece	euticals ar	nd herbal	2	2

#### Syllabus

Module 1	<b>Cosmetics – Regulatory:</b> 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
	for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.
Module 2	Design of cosmeceutical products: Sun protection, sunscreens classification and
	regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly
	sensitive teeth through cosmeceutical formulations
Module 3	<b>Formulation Building blocks:</b> Building blocks for different product formulations of
Module 3	<b>Formulation Building blocks:</b> Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients,
Module 3	<b>Formulation Building blocks:</b> Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as
Module 3	<b>Formulation Building blocks:</b> 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
Module 3	<b>Formulation Building blocks:</b> 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.
Module 3	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream,</li> </ul>
Module 3	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> </ul>
Module 3 Module 4	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> <li>Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU</li> </ul>
Module 3 Module 4	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> <li>Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.</li> </ul>
Module 3 Module 4	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> <li>Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.</li> <li>Controversial ingredients: Parabens, formaldehyde liberators, dioxane.</li> </ul>
Module 3 Module 4	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> <li>Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.</li> <li>Controversial ingredients: Parabens, formaldehyde liberators, dioxane.</li> <li>Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review</li> </ul>
Module 3 Module 4	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> <li>Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.</li> <li>Controversial ingredients: Parabens, formaldehyde liberators, dioxane.</li> <li>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</li> </ul>
Module 3 Module 4	<ul> <li>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.</li> <li>Formulation Building blocks: Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.</li> <li>Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.</li> <li>Controversial ingredients: Parabens, formaldehyde liberators, dioxane.</li> <li>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.</li> </ul>

SI No	Title	Author(s)	Publisher	Year
1	Handbook of cosmetic science and Technology	A.O.Barel, M.Paye and H.I. Maibach	CRC Press	2009
2	Cosmetics- Formulation, Manufacturing and Quality control	P.P. Sharma	Vandana Publishers	2008
3	The Complete Technology Book on Herbal Perfumes and Cosmetics	<u>H Panda</u>	NIR Project and Consultancy services	2005

#### Global Certifications: Nil

Mapped Global Certifications:								
SI	SI Titl Certification Proctored Format of the Exam URL of the							
No	е	Provider	(Y/N)	Exam	Provider	Certification		
1								

## Tools used in Practical / Skill:

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1	NA	NA	NA

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

## PHARMACEUTICS PRACTICAL II (PP-II)

COURSE CODE		22PY5111	MODE	R	LTPS	0-0-12-0	PRE-			Nil
							REQ	UISITE		
Course	Outcome	S								
CO#	CO# CO Description			В	BTL PO					
									Ma	apping
CO1	Demonstrate the practical skills in development and evaluation of novel systems Demonstrate the BA studies, PK-PD analysis, and IVIVC Apply computational tools in product development and optimization					of 4		3,6	5	
CO2	Understand the concept and application of PK-PD simulation models Understand the clinical data collection and population modeling Demonstrate the formulation and evaluation of cosmeceuticals				on 4		3,6	;		

#### Syllabus

Module	Contents
Module-I	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
Module-II	12. DoE Using Design Expert <sup>®</sup> Software
	13. Formulation data analysis Using Design Expert <sup>®</sup> 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

#### Reference Books: S. No Title Author(s) Publisher Year Gillbert and S. 1 **Modern Pharmaceutics** CRC Press Inc 2002 Banker. 2 Pharmaceutical Sciences. Remington Elsevier 2021

3	Adv	vances in Pharmace	H.S. Bean & Beckett.	A.H.	Acaden Inc.	nic Press	1997	
4	Ber	ntley's Textbook of F	Rawlins. Elsevie		Elsevier	r	2010	
Global	Certif	ications: NA						
Марр	oed Gl	obal Certifications:						
SI	Titl	Certification	Proctored	Format of the	ormat of the Exam			e
No	e	Provider	(Y/N)	Exam	xam Provider Certific			ion
1								

#### Tools used in Practical / Skill: NA

2

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1			
2			

Evaluation	Component	Weightage	Total
In-Sem	Attendance	6.65	
Formative	Lab continuous evaluation	6.65	13.3
In-Sem	Semester In lab exam-I	10	
Summative	Semester In lab exam-II	10	20
End-Sem	End Semester Exam		
Summative		66.7	66.7
		Grand Total	100
# RESEARCH METHODOLOGY AND BIOSTATISTICS (RMBS)

						<u> </u>	
COURSE CODE	22PY5113	MODE	R	LTPS	4-0-0-0	PRE-REQUISITE	Nil

#### **Course Outcomes**

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

#### Syllabus

Module 1	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 technique						
	<b>Biostatistics:</b> 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.						
Module 2	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						
	interact referral wonder relationships treatment of family members sevual						
	relationships fatality						
Modulo 2	CPCSEA guidelines for laboratory animal facility: Goals veterinary care, guarantine						
Would 5	surveillance diagnosis treatment and control of disease personal bygiene location of						
	animal facilities to laboratories anesthesia euthanasia physical facilities						
	environment animal husbandry record keeping SOPs personnel and training						
	transport of lab animals.						
Module 4	<b>Declaration of Helsinki:</b> History, introduction, basic principles for all medical research.						
	and additional principles for medical research combined with medical care.						

### Reference Books:

SI No	Title	Author(s)	Publisher	Year
1	Biostatistics and Research	N. K. Nag	Kalyani	2004
	methodology ,		Publishers	
2	Introduction to Biostatistics and	Ronald	Estern Economy	2013
	Research methodology,		Edition	

3	Pharmaceutical statistics- Practical	Sanford Bolton	Marcel Dekker	2013
	and clinical applications		Inc	
4	Fundamental of Statistics	S.C.Gupth	Himalaya Publishing House-	2014
5	Design and Analysis of Experiments –	Pannerselvam,	PHILearning	2015
	,R		Private Limited	

### Global Certifications:

Ma	pped Global Certifications:					
SI		Certificat	Procto	Format	Exam	
Ν		ion	red	of the	Provid	URL of the Certification
0	o Title	Provider	(Y/N)	Exam	er	
1	Applied Biostatistics Certificate: Methods & Applications	РСВ	YES	MCQs	Harvar d Catalys t	https://catalyst.harvard. edu/courses/biostatscer tificate/

### Tools used in Practical / Skill:

SI No	Tool Name	Parent Industry	Open Source/ Commercial
1	NA	NA	NA

Evaluation	Component	Weightage	Total
	Attendance	8	
In-Sem	Question and Answers	2	
Formative			10
In-Sem	Semester in Exam-I	7.5	15
Summative	Semester in Exam-II	7.5	
End-Sem	End Semester Exam	75	75
Summative			

### SEMINAR/ASSIGNMENT (S/A)

COURSE CODE 22PY5106 MODE R LTPS 0-0-8-0 PRE-REQUISITE NIL			-			X * 7	/	
	COURSE CODE	22PY5106	MODE	R	LTPS	0-0-8-0	PRE-REQUISITE	Nil

#### **Course Outcomes**

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

Evaluation	Component	Weightage	Total
End-Sem	End Semester Exam	100	100
Formative			

### SEMINAR/ASSIGNMENT (S/A)

						/	
COURSE CODE	22PY5112	MODE	R	LTPS	0-0-8-0	PRE-REQUISITE	Nil

#### **Course Outcomes**

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

Evaluation	Component	Weightage	Total
End-Sem	End Semester Exam	100	100
Formative			

# JOURNAL CLUB (JC)

			-				
COURSE CODE	22PY5114	MODE	R	LTPS	0-0-2-0	PRE-REQUISITE	Nil

#### Course Outcomes

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

Evaluation	Component	Weightage	Total
Sem-In	Sem-In Exam	25	25
Formative			

# DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION) (D/P)

COURSE CODE	22PY5115	MODE	R	LTPS	0-0-4-0	PRE-REQUISITE	Nil

### **Course Outcomes**

CO#	CO Description	BTL	PO Mapping
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

Evaluation	Component	Weightage	Total
Sem-In	Sem-In Exam	50	50
Formative			

# JOURNAL CLUB (JC)

					<u> </u>		
COURSE CODE	22PY5117	MODE	R	LTPS	0-0-2-0	PRE-REQUISITE	Nil

### **Course Outcomes**

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

Evaluation	Component	Weightage	Total
Sem-In	Sem-In Exam	25	25
Formative			

# DISCUSSION/FINAL PRESENTATION (D/P)

COURSE CODE	22PY5119	MODE	R	LTPS	0-0-6-0	PRE-REQUISITE	Nil

### **Course Outcomes**

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

Evaluation	Component	Weightage	Total
Sem-In	Sem-In Exam	75	75
Formative			

# CO-CURRICULAR ACTIVITIES (ATTENDING CONFERENCE, SCIENTIFIC PRESENTATIONS AND OTHER SCHOLARLY ACTIVITIES) (CCA)

COURSE CODE 22PY5120	MODE	R	LTPS	0-0-8-0	PRE-REQUISITE	Nil
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#### **Course Outcomes**

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

## **RESERCH WORK (RW)**

COURSE CODE	22PY5116	MODE	R	LTPS	0-0-28-0	PRE-REQUISITE	Nil

#### **Course Outcomes**

CO#	CO Description	BTL	PO Mapping
CO1	Conduct literature review and come to conclusions on selection of	2	2
	drugs/excipients/methods/techniques		
CO2	Develop a research protocol or plan of work	2	2
CO3	Conduct research experiments to meet the aim and objectives of	4	2, 3
	proposed research work		
CO4	Evaluate the findings and plan alterations or new methodologies	5	2, 3
	or procedures for further improvement		
CO5	Document the findings of conducted experiments	2	2
CO6	Interpret the results obtained and plan further activities	4	2
1		1	

Evaluation	Component	Weightage	Total
Sem-End	Sem-End Project	350	350
Summative			

## **RESERCH WORK (RW)**

COURSE CODE	22PY5118	MODE	R	LTPS	0-0-33-0	PRE-REQUISITE	Nil

### Course Outcomes

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

Evaluation	Component	Weightage	Total
Sem-End	Sem-End Project	400	400
Summative			