MOHAN BABU UNIVERSITY

Sree Sainath Nagar, Tirupati – 517 102

MBU
MOHAN BABU
UNIVERSITY
DREAM. BELIEVE. ACHIEVE

MB SCHOOL OF PHARMACEUTICAL SCIENCES

Master of Pharmacy in Pharmaceutics

MBU23 Academic Regulations and Curriculum
(Version 1.0)

(Applicable to M.Pharm Programs offered by MB School of Pharmaceutical Sciences in MBU from 2023-24 onwards)

Choice Based Credit System (CBCS)

MOHAN BABU UNIVERSITY

Vision

To be a globally respected institution with an innovative and entrepreneurial culture that offers transformative education to advance sustainability and societal good.

Mission

- Develop industry-focused professionals with a global perspective.
- Offer academic programs that provide transformative learning experience founded on the spirit of curiosity, innovation, and integrity.
- Create confluence of research, innovation, and ideation to bring about sustainable and socially relevant enterprises.
- Uphold high standards of professional ethics leading to harmonious relationship with environment and society.

MB SCHOOL OF PHARMACEUTICAL SCIENCES

Vision

To be a global leader in the field of Pharmaceutical Education and Health Care Management by providing Quality Education, Training, Research and Entrepreneurial Ecosystem.

Mission

- Developing competencies and skills to solve problems in the field of Pharmaceutical Sciences through contemporary Curriculum and congenial learning environment.
- Imbibing ethics and values in students for effective Pharmaceutical practice through curricular, co-curricular and extra-curricular activities.
- Encourage faculty and staff to excel in their respective fields and demonstrate the best of their abilities by way of continuing education, research and consultancy.

PROGRAM EDUCATIONAL OBJECTIVES

After few years of graduation, the graduates of M.Pharm. (Pharmaceutics) will:

PEO1: Enrolled or completed research in the core and competency areas of Pharmacy.

PEO2: Employed as productive and valued professional in industry/teaching/research.

PEO3: Successful Entrepreneur in the pharmaceutical and allied healthcare

PEO4: Continue to learn and adapt evolving technologies in the core or allied areas of Pharmaceutical sciences.

PROGRAM OUTCOMES

On successful completion of the Program, the graduates of M.Pharm. (Pharmaceutics) will be able to:

PO1. Apply **knowledge** of basic science and pharmaceutical science fundamentals to solve complex problems in pharmacy

PO2. **Analyse** the problems related to design, development and manufacturing of dosage forms.

PO3. **Design** drugs and drug delivery systems to meet desired needs considering public health and safety, and the cultural, societal, and environmental considerations

PO4. Understand and **solve complex problems** in pharmacy by conducting experimental investigations

PO5. Apply appropriate **methods and techniques** and understand utilization of resources appropriately to complex activities in pharmaceutical industry.

PO6. Understand the effect of pharmaceutical solutions on **legal, cultural, social, public health and safety** aspects relevant to the professional practice.

PO7. Work as an individual and as a member of a team, to plan and to integrate knowledge of various disciplines in pharmaceutical industry and to **lead teams in multidisciplinary settings**

PO8. Make effective **oral presentations and communicate** technical ideas to a broad audience using written and oral means

PO9. **Lead and manage** multidisciplinary teams by applying principles of new and ongoing projects for appropriate decision making.

PO10. **Adapt** to the changes and advancements in technology and engage in independent and **lifelong learning**

PROGRAM SPECIFIC OUTCOMES

After successful completion of the M.Pharm. (Pharmaceutics), the graduates will be able to:

PSO1: Apply appropriate tools and techniques for design and development of Pharmaceutical Dosage forms, cosmeceuticals and drug delivery systems.

PSO2: Comprehend the pharmacokinetic parameters of drugs, dose calculations and biopharmaceutical approaches in problem solving.

PSO3: Acquaint knowledge on investigational new drugs and regulatory submissions

PSO4: Create leaders in Pharmaceutical Sector.

1. Preamble

Modern era students would like to take decisions on their own and plan their future accordingly. Students would like to pursue education as per their pace. On other hand, employers expect multidisciplinary competency, leadership skills and computer literacy along with lifelong learning skills from the students. The conventional learning system has narrow scope with regard to flexibility in choosing courses of their choice to become a well-rounded personality. It is essential that the present education system should address this and provide wide opportunities for students to choose programs and courses of their interest in order to realize their full potential which in turn leads to the nation development. Further, natural resources are depleted globally at a faster rate. Hence, sustainable development has become the agenda for the complete world to preserve natural resources and environment for the sake of future generations. In addition, the world is embracing disruptive technologies to improve the quality of life. Also, students should be nurtured with skills on higher order cognitive capacities, research, innovation, incubation and entrepreneurship; life skills; social consciousness, inclusiveness, equality, culture, languages, literature, ethics and values; basic arts, crafts, humanities, games, sports and fitness.

In this context, Mohan Babu University has taken initiative and brought out Academic Regulations addressing Choice Based Credit System, sustainable development, disruptive technologies, rapid change in knowledge landscape, change in employment landscape, change in global ecosystem and other areas of national and international importance to change country's educational landscape and in turn country's landscape.

MBU23 Academic Regulations embrace Choice Based Credit System, project-based learning, enhanced practical component, etc.

2. Scope

The rules and regulations stated herein shall be called "MBU23 Academic Regulations" in its complete form. MBU23 academic regulations as given in this document are applicable to students admitted in PG Programs offered under MBU from the academic year 2023-24 onwards. All academic programs under MBU23 shall be decided by the Academic council. MBU23 is applicable for both existing as well as new programs offered by the MBU, until and unless it is explicitly stated.

3. Regulations for all M. Pharm Programs offered under MBU

These regulations shall be called "The Regulations for the M. Pharm Degree Program (CBCS)". They shall come into effect in the academic year 2023–24. The regulations framed are subject to modifications from time to time by Mohan Babu University (MBU) in line with the Pharmacy Council of India (PCI) regulations.

4. Choice Based Credit System (CBCS)

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

5. Definitions and Nomenclature

'***Degree***' means the academic award conferred upon a student on successful completion of any program of study designed to achieve the defined attributes.

'***Program***' means cohesive arrangement of courses, co-curricular and extracurricular activities to accomplish predetermined objectives leading to the awarding of a degree in a branch or discipline. Some Degree programs also provide options to specialize in a specific domain of interest in a branch or discipline.

'***Course***' means any combination of lecture, tutorial, practical and project-based learning sessions of a subject studied in a semester, like Pharmaceutics, Pharmaceutical Analysis, Pharmacology and Pharmacognosy etc.

6. Admission

6.1 Number of Seats: The number of seats in M.Pharm program for which admission is to be made in each department will be decided by the Board of Management, MBU with approval from Pharmacy Council of India.

6.2 Nationality and Age:

Resident Indian or Non-Resident Indian (NRI), holder of PIO or OCI card issued by Government of India is eligible to apply for Selection Process.

Note: NRIs, holders of PIO or OCI card issued by Government of India must apply under international student category only.

Student should have attained the age of 21+ years on the 31st December of the year in which he/she is seeking admission.

6.3 Eligibility Criteria for M. Pharm Program

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 (Bachelor of Pharmacy)

Candidates with valid scores in National level entrance exams like GPAT, is eligible for direct admission in M. Pharmacy

6.4 Authority for Admission

Any matter related to admission to any program, the decision of the Admission Committee is final.

If, at any time after admission, it is found that a candidate has not fulfilled the requirements stipulated in the offer of admission, the concerned School Dean may revoke the admission of the candidate and report the matter to the Vice Chancellor.

In Addition to the above, admissions will be based on the rules and regulations of the UGC/Competent authorities in force at the time of admissions.

7. M. Pharm. Specializations offered by MB School of Pharmaceutical Sciences

School	Programs
MB School of Pharmaceutical Sciences	M.Pharm. (Pharmaceutics)
	M.Pharm. (Pharmaceutical Analysis)

8. Academic System

8.1 Semester system:

M. Pharmacy programs offered by MB School of Pharmaceutical Sciences shall follow the Semester system. There will be two semesters in an academic year and the Program is for 4 semesters (two academic years).

8.2 Curriculum

The university Academic Regulations shall have 5-digit alpha-numeric representation that refers to University Name followed by last two digits of Calendar Year viz. MBU23 Regulations. Program Curriculum shall have the corresponding Academic Year representation. Students admitted into a program shall adopt a curriculum specified by the Academic Council for that academic year. Unless otherwise stated explicitly by the Academic Council, any curriculum changes will be applicable to the students admitted in the subsequent year and the existing batches continue to follow the curriculum prescribed at the time of their joining the program.

8.3 Course Classification

Courses may be classified as Theory, Practical, Seminar, Journal Club, Proposal Presentation, Dissertation Presentation and Research Work.

8.4 Course Credit Assignment

Credits shall be assigned to each Course with L: T: P: C (Lecture Hours: Tutorial Hours: Practical Hours: Credits) Structure, as defined below:

- ✓ Theory Course: One Lecture Hour (L) per week in a semester: 01 Credit
- ✓ Practical Course: One Practical Hour (P) Per week in a semester: 0.5 Credit
- ✓ Tutorial: One Tutorial Hour (T) Per week in a semester: 01 Credit

The contact periods are not specified for the courses like Seminar, Journal Club Proposal Presentation, Dissertation Presentation and Research Work. However, credits assigned are based on complexity of work.

8.5 Syllabus

The syllabus of a course provides what the student will learn in the course of study. Each course syllabus document contains course code, course title, L T P C, course description, course outcomes, module-wise topics, duration to cover each module, text books, reference books, video lectures and web resources for additional learning.

8.6 Course Handout

A Course Handout consists of a detailed plan of lectures and its mode of delivery, List of Exercises/Experiential learning, Resources, Evaluation methods, Model Question paper and CO Attainment Targets.

9. Academic Calendar

The academic calendar includes the dates with regard to course registrations, spell of instructions, continuous internal assessment tests, semester-end theory examinations, practical examinations and semester holidays. The Registrar will communicate the Academic calendar to the Departments/ Schools, and the same will be available on the website. The dates and schedules in the academic calendar may change in specific programs due to regulatory and local requirements. In such cases, the concerned School Dean with prior authorization will communicate the changes to the students. The revised academic calendar will also made available on the website.

10. Course Registration

Immediately after joining the University, each student shall be assigned a Mentor by the Department/School concerned. The mentor shall discuss with the student on their academic performance semester-wise, periodically, and guide the student on nature and number of courses to be registered in the ensuing semester, within the framework of that program curriculum.

- Through the course registration process, every semester, it is mandatory for the students to register for the courses specified in the semester as and when notified, with the approval of the mentor.
- The students may be asked to undergo non-credited Bridge Courses for necessary fundamental disciplines as recommended by the program curriculum.
- Students shall not be permitted to register for the courses if the student has any outstanding dues to the University.
- For registering IV Semester End Examinations, the student is eligible only if he/she successfully completed all courses till III-Semester as per their program course structure.

10.1 Arrear Examination:

- If a student failed in a course, then the student is allowed to register for arrear examinations as and when notified.
- If a student has backlog courses after completion of the program of study, a provision is given to clear the courses by appearing any number of arrear examinations upon the notifications within the stipulated program duration as mentioned in section 18.

11. Attendance Requirements

- A student shall be eligible to appear for semester-end examinations if he acquires a minimum of 80% of attendance in aggregate of all the courses in a semester.
- Condonation of shortage of attendance in aggregate up to 10% (70% and above and below 80%) in each semester may be granted by the School Dean.
- Shortage of attendance below 70% in aggregate shall in no case be condoned.
- Students whose shortage of attendance is not condoned in any semester shall not be eligible to take their semester-end examination and their registration shall stand cancelled.
- Student shall not be promoted to the next semester unless he satisfies the attendance requirements of the semester, as applicable. The student may seek readmission for the semester when offered next. He will not be allowed to register for the courses of the semester while he is in detention.
- Stipulated fee shall be payable to the college towards condonation of shortage of attendance.
- In the remaining 20% of attendance, the student shall manage medical/personnel/ casual/official absence for organizing events/ seminars/ workshops/ technical/ cultural festivals/ competitions/ participation in co-curricular/ extra-curricular events or any other reason.

12. Evaluation Criteria

12.1 Scheme of Evaluation

All components in any Program of Study shall be evaluated through Internal Evaluation and/or Semester End Evaluation.

<table>
<tr><th>Course Type</th><th>Marks</th><th colspan="2">Examination and Evaluation</th><th>Scheme of Examination</th></tr>
<tr><td rowspan="4">Theory</td><td rowspan="3">25</td><td>15</td><td>Mid Examination
(60 Minutes)</td><td>Two Mid Examinations each for 30 marks shall be conducted and each shall be scaled to 15 marks.
• The question paper for Mid-I & Mid-II shall be of descriptive type with two parts i.e., Part A and Part B
• Part A contains 4 short answer questions [(Q 1 (a) to (d)] out of which student shall be answering 3 questions and evaluated each for 5 marks
• Part B contains 2 long answer questions [(Q 2 (a) to (b)] out of which student shall be answering 1 question and evaluated for 15 marks.</td></tr>
<tr><td>10</td><td>Continuous Assessment</td><td>The student shall be assessed based on the following parameters two times in a semester.
• Attendance – Max. 4 Marks
<table>
<tr><th>Percentage of Attendance</th><th>Marks</th></tr>
<tr><td>95 – 100</td><td>4</td></tr>
<tr><td>90 – 94</td><td>3</td></tr>
<tr><td>85 – 89</td><td>2</td></tr>
<tr><td>80 – 84</td><td>1</td></tr>
<tr><td>Less than 80</td><td>0</td></tr>
</table>
• Academic activities – Max. 3 Marks
(Average of any 3 activities Eg. Quiz, Assignment, Open Book Test, Fieldwork, Group Discussion and Seminar)
• Student-Teacher interaction – Max. 3 Marks</td></tr>
<tr><td colspan="3">For a total of 25 Marks, the average of sum of Mid-I & First Continuous Assessment marks and sum of Mid-II & Second Continuous Assessment marks shall be considered.</td></tr>
<tr><td>75</td><td colspan="2">Semester End Examination
(180 Minutes)</td><td>The examination shall be conducted for 75 marks
The question paper shall of descriptive type with two parts i.e., Part-A and Part-B.
Part-A shall contain 8 short answer questions [Q. No. 1 (a) to (h)] out of which student should be answering 6 question and evaluated each for 5marks.
Part-B shall contain Five questions [totally Ten questions from Q. No. 2 to 6)] of which student has to answer 3 questions and shall be evaluated each for 15 marks.</td></tr>
</table>

<table>
<tr><th>Course Type</th><th>Marks</th><th colspan="2">Examination and Evaluation</th><th>Scheme of Examination</th></tr>
<tr><td rowspan="4">Practical</td><td rowspan="3">50</td><td>10</td><td>Day-to-day Evaluation</td><td>Day-to-day evaluation based on the performance in the conduction of laboratory experiments and its records & Viva voce for 10 Marks</td></tr>
<tr><td>10</td><td>Attendance</td><td><table><tr><th>Percentage of Attendance</th><th>Marks</th></tr><tr><td>95 – 100</td><td>10</td></tr><tr><td>90 – 94</td><td>7.5</td></tr><tr><td>85 – 89</td><td>5</td></tr><tr><td>80 – 84</td><td>2.5</td></tr><tr><td>Less than 80</td><td>0</td></tr></table></td></tr>
<tr><td>30</td><td>Internal Examination
(4 Hours)</td><td>• One Internal Examination shall be conducted for 30 marks
• Evaluation shall be on the following parameters.
➢ Part A – Synopsis for 5 marks
➢ Part B – Major Experiment for 15 marks,
➢ Part C – Minor experiment for 5 marks
➢ Part D – Viva voce for 5 marks.
The distribution of marks may be altered as per the course requirement.</td></tr>
<tr><td>100</td><td colspan="2">Semester End Examination
(8 Hours)</td><td>• Evaluation shall be on the following parameters.
➢ Part A – Synopsis for 20 marks
➢ Part B – Major Experiment for 40 marks,
➢ Part C – Minor experiment for 20 marks
➢ Part D – Viva voce for 20 marks.
The distribution of marks may be altered as per the course requirement.</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td>Seminar</td><td>100</td><td colspan="2">Semester End Examination</td><td>Detailed in Section 12.2</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td>Journal Club</td><td>25</td><td colspan="2">Internal Assessment</td><td>The student shall refer Two Journal Papers and the synopsis of each article shall be presented to Evaluation Committee (EC). Each presentation shall be evaluated for 25 marks. For a total of 25 marks, 80% of better one of the two and 20% of the other one are added and finalized.</td></tr>
<tr><td colspan="5"></td></tr>
</table>

Proposal Presentation	50	Internal Assessment	A student has to identify the topic of the Research, after thorough relevant Literature survey. The same shall be presented to the Project Evaluation Committee (PEC). The performance of the student shall be evaluated on the basis of TWO reviews along with detailed discussions. Each review shall be conducted for a maximum of "50" marks. For a total of 50 marks, 80% of better one of the two and 20% of the other one are added and finalized.
Dissertation Presentation	75	Internal Assessment	A student has to present the progress of the Research Work to the Project Evaluation Committee (PEC). The performance of the student shall be evaluated on the basis of TWO reviews along with detailed discussions. Each review shall be conducted for a maximum of "75" marks. For a total of 75 marks, 80% of better one of the two and 20% of the other one are added and finalized.
Research work Phase-I	350	Semester End Examination	Detailed in Section 12.3
Research work Phase-II	400	Semester End Examination	Detailed in Section 12.4

12.2 Seminar

The student shall collect information through literature survey on a specialized topic and prepare a technical report, showing his understanding of topic, and submit it to the seminar evaluation committee (SEC) followed by a presentation of the same shall be made before the SEC and shall be evaluated for 100 marks.

The report and presentation shall be evaluated at the end of semester by Seminar Evaluation Committee (SEC) consisting of concerned supervisor and senior faculty member of the department nominated by Head of the department with the approval of respective school dean. If required, multiple SECs shall be constituted for multiple sections with prior approval.

12.3 Research work Phase-I

A student has to take up and complete Research Work–Phase I in III-Semester. He/she has to identify the topic of the Project Work, collect relevant Literature, preliminary data, implementation tools/ methodologies etc., and perform a critical study and analysis of the problem identified and submit a Report.

The Research Evaluation Committee (REC) consisting of concerned supervisor and two senior faculty members shall monitor the progress of the project work of the student. The PEC is constituted by the respective School Dean on the recommendations of the Head of the Department.

Semester end Evaluation: The performance of the student shall be evaluated in semester-end examination by the concerned guide and a senior faculty member recommended by the Head of the

Department and appointed by the respective Dean of the School based on the following parameters

Objective of the work	50 Marks
Problem Identification	75 Marks
Methodology	100 Marks
Presentation of work	50 Marks
Communication Skills	25 Marks
Viva-Voce	50 Marks
Total	**350 Marks**

12.4 Research work Phase-II

A student shall continue Research Work–Phase I in order to undertake the Research Work Phase II during the IV-Semester by extending practical investigations, implementation, analysis of results, validation and report writing. The student shall submit a Project report at the end of the semester after approval of the REC.

Semester End Evaluation:

The student is eligible for registering IV Semester End Examinations only if he/she successfully completed all courses till III-Semester as per their program course structure.

A candidate shall be allowed to submit the dissertation/Thesis report on the recommendations of the REC. Four copies of the dissertation certified in the prescribed format by the concerned Supervisor and HOD shall be submitted to the Department. One copy is to be submitted to the Controller of Examinations and one copy to be sent to the examiner. The examiner shall be nominated by the School Dean from the panel of THREE examiners submitted by the Department for a maximum of 5 students at a time for adjudication.

The performance of the student shall be evaluated in semester-end examination by the concerned guide and a senior faculty member recommended by the Head of the Department and appointed by the respective School Dean based on the following parameters

Methodology Adopted	100 Marks
Results	100 Marks
Conclusions and Outcomes	75 Marks
Presentation of work	50 Marks
Communication Skills	25 Marks
Viva-Voce	50 Marks
Total	**400 Marks**

- The guidelines for preparing dissertation/thesis report shall be notified through respective Program Head from time to time.
- The Thesis report shall be subjected to plagiarism check and the report is accepted only if it is less than 20%.
- It is mandatory that every student has to publish/submit acceptance letter of a paper in a peer

reviewed Journal or Conference before IV Semester End Examinations. Otherwise, the student is not eligible for submission of thesis report.

- If the report of the examiner is favourable, Semester-end Project Work Phase-II Viva-Voce Examination shall be conducted by a Committee consisting of External examiner (nominated by the School Dean), HOD and concerned Supervisor at the end of the IV-Semester.
- If the report of the examiner is not favourable, the dissertation should be revised and resubmitted after a minimum period of three months.
- The students who fail in Research work Phase-I (or) Phase-II Viva-Voce examination shall have to re-appear for the Viva-Voce examination after three months.
- Extension of time for completing the project is to be obtained from the Academic Council, MBU.
- Change of the research work topic shall be permitted only in Research Work Phase-I, within FOUR weeks after commencement of the III-Semester with the approval of the REC.

12.5. Recounting /Revaluation/Personal Verification/ Challenging Evaluation:

Students shall be permitted to apply for Recounting /Revaluation/Personal Verification/ Challenging Evaluation of the Semester End Examination answer scripts within a stipulated period after payment of the prescribed fee. After completion of the process of Recounting/ Revaluation/Personal Verification/ Challenging Evaluation, the records are updated with changes if any, and the student shall be issued a revised grade sheet. If there are no changes, the student shall be intimated the same through a notice.

12.6 Improvement of Internal Assessment

A student shall have the opportunity to improve his/ her performance only once in the mid exam component of internal assessment. The reconduct of mid exam shall be completed before the commencement of immediate next semester.

13. Course Wise Grading of Students

Each student shall be awarded Letter Grades and Grade Points (GP) based on the aggregate of marks obtained through Internal Evaluation and Semester End Evaluation in a course.

13.1 *Absolute Grading*

Based on the performance, each student shall be awarded a final letter grade at the end of semester for each course. The letter grades and their corresponding grade points are given in table no 4.

Letter Grades and Corresponding Grade Points equivalent to percentage of marks

% of Marks obtained	Letter Grade	Performance	Grade Points (GP)
≥90	O	Outstanding	10
≥80 to <90	A	Excellent	9
≥70 to < 80	B	Good	8
≥ 60 to < 70	C	Fair	7
≥ 50 to < 60	D	Average	6
<50	F	Fail	0
Absent	Ab	Fail	0

A student is considered to have successfully completed a course and earned the credits if he / she secured a letter grade other than "F" or "Ab" in that course. A letter grade "F" or "Ab" in any course implies a failure in that course. The student should reappear for the said examination in the due course.

Pass Marks: In Absolute Grading, a student shall be declared as "PASS" in a course if he/she secures a minimum of 50% of the total marks obtained from Internal assessment and Semester End Evaluation. Otherwise, he/she shall be declared as "FAIL" in that course.

***13.2 Semester Grade Point Average (SGPA*):** SGPA shall be calculated as given below on a "10 point scale" as an index of the student's performance:

$$SGPA = \frac{\sum(C\ X\ GP)}{\sum C}$$

Where "C" denotes the "credits" assigned to the courses undertaken in that semester and "GP" denotes the "grade points" earned by the student in the respective courses.

Note: SGPA is calculated only for the candidates who appeared in the semester-end regular examinations in a particular semester.

***13.3 Cumulative Grade Point Average (CGPA*):**

The CGPA shall be calculated for a candidate who appeared in the Semester End Examination (including Regular & Arrear) till that semester. The CGPA shall be displayed in the Grade sheet of the Regular Semester-end examinations and also in the consolidated Grade Sheet issued at the end of the program. The CGPA is computed on a 10-point scale as given below:

$$CGPA = \frac{\sum(C\ X\ GP)}{\sum C}$$

Where, C denotes the credits assigned to courses undertaken up to the end of the Program and GP denotes the grade points earned by the student in the respective courses.

Both SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.

13.4 Award of Class – The CGPA requirement for the award of class is as follow

CGPA requirement - Awarding of Class

CGPA Secured	Class Awarded
≥ 7.5	First Class with Distinction
≥6.0 and <7.49	First Class
≥5.0 and <5.99	Second Class

14. Grade Sheet

A grade sheet shall be issued to each student indicating the SGPA and CGPA, provided if he passed all the courses registered in the regular semester-end examinations.

15. Consolidated Grade Sheet

After successful completion of the entire Program of study, a Consolidated Grade Sheet indicating the performance in all academic years shall be issued as a final record. Duplicate Consolidated Grade Sheet shall also be issued, if required, after payment of the requisite fee.

16. Withholding of Results

Results may be withheld in a semester, if

- The student has any dues to the Department/ School/ University
- Action arising out of malpractice is pending
- Action arising out of indiscipline is pending
- The student whose result was withheld shall not be allowed/promoted to the next higher semester.

17. Credit Transfer

- If a student discontinued in any of the semester and later, he wishes to continue in the same program, then the he shall follow the latest regulations and curriculum that is being implemented during readmission into the same semester. However, the earned credits before discontinued shall be transferred to his credit account and he has to complete his degree within the stipulated program duration as mentioned in section 18.
- A similar procedure shall be adopted for the candidates who are seeking admission from other universities into various eligible programs of the University, subject to the condition that those Universities are recognized and approved for credit transfer by MBU.
- If the other Universities follow a different system, then the program School into which the student is seeking admission/ transfer shall work out on equivalence of credits that are to be transferred with valid supporting documentation.
- The number of credits thus transferred will be considered for the minimum credit requirements of the program, but not considered for the GPA/ CGPA calculations. The credits thus transferred will be indicated as total credits at the bottom of the Consolidated Grade Sheet as 'Total Credits Transferred from (Name of the Institute, place and Country)' and no breakup of courses will be listed.
- Award of degree classification is purely based on the GPA/CGPA calculations considering credits earned during the program of study with the MBU.

18. Program Duration

Minimum Duration: The minimum duration for M. Pharm Program is detailed below
A student is said to be completed the program only if he/she earns required credits, as specified in their program curriculum. However, the degree shall be awarded only upon the completion of minimum duration of the program concerned.

Maximum Duration: if a student has backlog courses even after the completion of the minimum duration limit, an additional grace period equivalent to double the period of minimum duration of the program of study shall be extended. Under no circumstances, the period of study shall be extended beyond the above limit and thereafter his/her studentship stands cancelled automatically. No separate intimation in this regard will be sent to the student.

19. Award of Degree

Eligibility: A student shall be eligible for the award of M.Pharm. Degree if he fulfills all the following conditions:

- Registered and successfully completed all the components prescribed in the Program of study to which he is admitted.
- Successfully acquired the minimum required credits as specified in the curriculum corresponding to the Program of study within the stipulated time.
- Obtained CGPA greater than or equal to 5.0 (Minimum requirement for declaring as passed).
- Has NO DUES to the University, Hostel, Library etc. and to any other amenities provided by the University.
- No disciplinary action is pending against him.

After successful completion of the program and minimum credit requirements as specified in the program curriculum, a Provisional Certificate will be issued to eligible students. The degree will be conferred on the student during the subsequent Convocation.

20. Amendments to Regulations

The Academic Council headed by the Vice-Chancellor of the University has the right to revise, amend, or change any component of regulations from time to time. In case of any dispute arising in interpreting the rules, the Academic Council's interpretation shall be the final decision.

21. General

The words such as "he", "him", "his" and "her" shall be understood to include all students irrespective of gender connotation.

Note: Failure to read and understand the regulations is not an excuse.

GUIDELINES FOR DISCIPLINARY ACTION FOR MALPRACTICES /

IMPROPER CONDUCT IN EXAMINATIONS

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the course of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the course of the examination)	Expulsion from the examination hall and cancellation of the performance in that course only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that course only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the course of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that course and all other courses the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the courses of that Semester. The Hall Ticket of the candidate is to be cancelled.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred for four consecutive semesters from class work and all Semester-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the courses of the examination (including labs and project work) already appeared and shall not be

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
		allowed to appear for examinations of the remaining courses of that semester. The candidate is also debarred for four consecutive semesters from class work and all Semester-end examinations, if his involvement is established. Otherwise, The candidate is debarred for two consecutive semesters from class work and all Semester-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that course and all the other courses the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the courses of that semester. The candidate is also debarred for two consecutive semesters from class work and all Semester-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that course only.
6.	Refuses to obey the orders of the Chief Controller of Examinations/Controller of Examinations/any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the Controller of Examinations or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that course and all other courses the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the courses of that semester. If the candidate physically assaults the invigilator/Controller of the Examinations, then the candidate is also debarred and forfeits his/her seat. In case of outsiders, they will be handed over to the police and a police case is registered against them.

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
	Controller of Examinations, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that course and all the other courses the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the courses of that semester. The candidate is also debarred for two consecutive semesters from class work and all Semester-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that course and all other courses the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the courses of that semester. The candidate is also debarred and forfeits the seat.

Note: Whenever the performance of a student is cancelled in any course(s) due to Malpractice, Then it shall be treated as failed in that course.

Course structure

M.Pharm. (Pharmaceutics)

I Semester

S. No.	Course Code	Course Title	Contact Periods per Week				Credits (c)	Scheme of Examination Max. Marks		
			L	T	P	Total		Int. Marks	Ext. Marks	Total Marks
1.	23PA201001	Modern Pharmaceutical Analytical techniques	4	-	-	4	4	25	75	100
2.	23PH201001	Drug Delivery System	4	-	-	4	4	25	75	100
3.	23PH201002	Modern Pharmaceutics	4	-	-	4	4	25	75	100
4.	23PH201003	Regulatory Affairs	4	-	-	4	4	25	75	100
5.	23PH205001	Pharmaceutics Practical I			12	12	6	50	100	150
6.	23PH211001	Seminar I	-	-	-	-	4	-	100	100
		Total	**16**	**-**	**12**	**28**	**26**	**150**	**500**	**650**

II Semester

S. No.	Course Code	Course Title	Contact Periods per Week				Credits (c)	Scheme of Examination Max. Marks		
			L	T	P	Total		Int. Marks	Ext. Marks	Total Marks
1	23PH201004	Molecular Pharmaceutics	4	-	-	4	4	25	75	100
2	23PH201005	Advanced Biopharmaceutics and Pharmacokinetics	4	-	-	4	4	25	75	100
3	23PH201006	Computer Aided Drug Delivery System	4	-	-	4	4	25	75	100
4	23PH201007	Cosmetics and Cosmeceuticals	4	-	-	4	4	25	75	100
5	23PH205002	Pharmaceutics Practical II			12	12	6	50	100	150
6	23PH211002	Seminar II	-	-	-	-	4	-	100	100
		Total	**16**	**-**	**12**	**28**	**26**	**150**	**500**	**650**

III Semester

S. No.	Course Code	Course Title	Contact Periods per Week				Credits (c)	Scheme of Examination Max. Marks		
			L	T	P	Total		Int. Marks	Ext. Marks	Total Marks
1	23PY201001	Research methodology and Biostatistics	4	-	-	4	4	25	75	100
2	23PH211003	Journal Club I	-	-	-	-	1	25		25
3	23PH211004	Proposal Presentation	-	-	-	-	2	50		50
4	23PH209001	Research Work Phase I	-	-	-	-	14	-	350	350
Total			**4**	**-**	**-**	**4**	**21**	**100**	**425**	**525**

IV Semester

S. No.	Course Code	Course Title	Contact Periods per Week				Credits (c)	Scheme of Examination Max. Marks		
			L	T	P	Total		Int. Marks	Ext. Marks	Total Marks
1.	23PH211005	Journal Club II	-	-	-	-	1	25		25
2.	23PH211006	Dissertation Presentation	-	-	-	-	3	75		75
3.	23PH210001	Research Work Phase II	-	-	-	-	16	-	400	400
Total			**-**	**-**	**-**	**-**	**20**	**100**	**400**	**500**

I SEMESTER

Course Code	Course Title	L	T	P	C
23PA201001	**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

COURSE DESCRIPTION: This course is designed to impart various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Demonstrate the fundamental concepts, Instrumentation and applications of absorption & emission Spectroscopy

CO2. Comprehend the fundamental concepts, Instrumentation and applications of NMR & Mass spectroscopic methods.

CO3. Demonstrate the fundamental concepts, Instrumentation and applications of diverse chromatographic techniques.

CO4. Understand the basic concepts, Instrumentation and applications of Electrophoresis& X-ray diffraction techniques.

CO5. Attain knowledge on immunological assays and its application

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	3	-	1	-	-	-	-	-	-	2	-	-	-
CO2	3	3	-	1	-	-	-	-	-	-	2	-	-	-
CO3	3	3	-	1	-	-	-	-	-	-	2	-	-	-
CO4	3	3	-	1	-	-	-	-	-	-	2	-	-	-
CO5	3	3	-	1	-	-	-	-	-	-	2	-	-	-
Course Correlation Mapping	**3**	**3**	**-**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**2**	**-**	**-**	**-**

Correlation Levels: ***3: High;*** ***2: Medium;*** ***1: Low***

COURSE CONTENT

Module 1: BASIC TYPES OF SPECTROSCOPY ***(11 Periods)***

a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.
c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.

Module 2: NMR SPECTROSCOPY ***(11 Periods)***

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

Module 3: MASS SPECTROSCOPY ***(11 Periods)***

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

Module 4: CHROMATOGRAPHY ***(11 Periods)***

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following

Paper chromatography, Thin layer chromatography, Ion exchange chromatography, Column chromatography, Gas chromatography, High Performance Liquid chromatography, Affinity Chromatography

Module 5: ELECTROPHORESIS & X-RAY CRYSTALLOGRAPHY ***(11 Periods)***

A) Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   Paper electrophoresis, Gel electrophoresis, Capillary electrophoresis, Zone electrophoresis, Moving boundary electrophoresis, Iso electric focusing.
B) X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

Module 6: IMMUNOLOGICAL ASSAYS ***(05 Periods)***

Immunological assays: RIA (Radio Immnumo assay) ELISA, Bioluminescence assays

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982

VIDEO LECTURES:

1. https://share.graphyapp.co/qVZ5
2. https://amzn.to/2XacNUG
3. https://www.youtube.com/channel/UCU91...

WEB RESOURCES:

1. https://share.graphyapp.co/qVZ5
2. https://www.amazon.in/shop/Dr.Puspend...

Course Code	Course Title	L	T	P	C
23PH201001	**DRUG DELIVERY SYSTEM**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

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

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Demonstrate and analyze sustain release and controlled release drug delivery system with employing advanced technologies**.**

CO2. Understanding the basics of site specific rate-controlled drug delivery systems.

CO3. Demonstrate and analyze Novel drug delivery system.

CO4. Demonstrate and analyze Protein drug delivery system.

CO5. Understanding the basics of Vaccine delivery system**.**

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	2	3	-	2	1	-	-	-	-	3	-	-	1
CO2	3	2	3	-	1	-	-	-	-	-	3	-	-	1
CO3	3	2	2	-	1	-	-	-	-	-	3	-	-	1
CO4	3	2	2	-	1	-	-	-	-	-	3	-	-	1
CO5	3	-	1	-	-	1	-	-	-	-	3	-	-	1
Course Correlation Mapping	**3**	**2**	**2**	**-**	**1**	**1**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**1**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: SUSTAINED RELEASE AND CONTROLLED RELEASE SYSTEMS *(12 Periods)*

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, Tele Pharmacy

Module 2: RATE CONTROLLED DRUG DELIVERY SYSTEMS *(12 Periods)*

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

Module 3: GASTRO-RETENTIVE & BUCCAL DRUG DELIVERY SYSTEMS *(12 Periods)*

Gastro-Retentive Drug Delivery Systems: Principle, concepts, advantages and disadvantages, Modulation of GI Transit time approaches to extend GI transit

Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Module 4: OCCULAR & TRANSDERMAL DRUG DELIVERY SYSTEMS *(12 Periods)*

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

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

Module 5: PROTEIN, PEPTIDE AND VACCINE DELIVERY SYSTEMS *(12 Periods)*

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

Vaccine delivery systems: Vaccines, Uptake of antigens, single Shot Vaccines, Mucosal and transdermal delivery of vaccines

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York,1992
2. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/ Weinheim.
3. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in2001)

VIDEO LECTURES:

1. https://youtu.be/W9lqUFWjsH8
2. https://youtu.be/2-kD9YtoJbw
3. https://youtu.be/4L8kUNdtRnM
4. htps://youtu.be/xXZPsp6Iilo
5. https://youtu.be/RjKqEEwn2-c

WEB RESOURCES:

1. https://www.researchgate.net/file.PostFileLoader.html?id=5768e197b0366d397470cfb7&assetKey=AS%3A375305815511042%401466491287686

COURSE CORE

Course Code	Course Title	L	T	P	C
23PH201002	**MODERN PHARMACEUTICS**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

COURSE DESCRIPTION: Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Demonstrate & apply physicochemical properties of drug substances in development of dosage forms

CO2. Understanding the concept validation equipment and pharmaceuticals**.**

CO3. Apply TQM & GMP Principles in pharmaceutical dosage forms.

CO4. Understand the physics of tableting technology & Invitro evaluation by applying statistical tools.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	2	2	-	2	-	-	-	-	-	3	-	-	-
CO2	3	3	1	-	2	-	-	-	-	-	3	-	-	-
CO3	3	2	1	2	1	-	-	-	-	-	3	-	-	-
CO4	3	1	2	1	1	-	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**2**	**2**	**1**	**2**	**-**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: PREFORMULATION AND OPTIMIZATION ***(20 Periods)***

Preformulation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

Optimization techniques - Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

Module 2: VALIDATION ***(10 Periods)***

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

Module 3: CURRENT GOOD MANUFACTURING PRACTICES ***(10 Periods)***

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

Module 4: COMPRESSION AND COMPACTION ***(10 Periods)***

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

Module 5: CONSOLIDATION PARAMETERS ***(10 Periods)***

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

Total Periods: 60

RESOURCES

TEXT BOOKS:

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

VIDEO LECTURES

1. https://youtu.be/nhbX-aEEwYE
2. https://youtu.be/ICcVaVhkM-g
3. https://youtu.be/mk2cQy4v4Nc
4. https://youtu.be/7IVr0A8y2Fs

WEB RESOURCES:

1. http://www.ich.org/
2. http://www.fda.gov/
3. https://www.scribd.com/document/424229842/Modern-Pharmaceutics

Course Code	Course Title	L	T	P	C
23PH201003	**REGULATORY AFFAIRS**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

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

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Understand the various documentation processes in drug development stages with respect to pharmaceutical industry.

CO2. Understand and familiarize various drug regulations related to pharmaceuticals in different countries.

CO3. Understand and develop skills required to learn post approval regulatory affairs and combinational products and medical devices.

CO4. Understand the Clinical and Nonclinical drug development process.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	-	1	-	-		-	-	-	-	3	-	-	-
CO2	3	-	1	-	-	3	-	-	-	-	3	-	-	-
CO3	3	-	1	-	-		-	-	-	-	3	-	-	-
CO4	3	-	1	-	-	3	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**-**	**1**	**-**	**-**	**3**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: DOCUMENTATION & REGULATORY REQUIREMENTS ***(15 Periods)***

a. **Documentation in Pharmaceutical industry**: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.
b. **Regulatory Requirements:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

Module 2: REGULATORY REQUIREMENT FOR PRODUCT APPROVAL ***(15 Periods)***

CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries

Module 3: NON CLINICAL DRUG DEVELOPMENT ***(15 Periods)***

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

Module 4: CLINICAL DRUG DEVELOPMENT ***(15 Periods)***

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

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams

VIDEO LECTURES

1. https://youtu.be/rN0igCCw3XM
2. https://youtu.be/KXLsHCX5
3. https://youtu.be/VBiwC-BanRY
4. https://youtu.be/9baBjcOP02Y
5. https://youtu.be/2eVwOJE3Aio
6. https://youtu.be/ly_HqDTZ_cM

WEB RESOURCES

1. www.ich.org/
2. www.fda.gov/
3. https://www.iptsalipur.org/wpcontent/uploads/2020/08/BP702T_IP_III.pdf
4. https://www.slideshare.net/PRABU12345678/non-clinical-drug-development - ppt
5. https://www.slideshare.net/drashutoshtiwari/clinical-trial-phases
6. https://www.slideshare.net/RISHABHAGRAWAL90/cmc- post approval-regulatory-affairs-ppt-119356077

COURSE CORE

Course Code	Course Title	L	T	P	C
23PH205001	**PHARMACEUTICS PRACTICAL-I**	**-**	**-**	**12**	**6**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

COURSE DESCRIPTION: Course if designed to impart advanced knowledge in the analysis of pharmacopoeia compounds and their formulations by Instrumental Methods.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Demonstrate and analyze various pharmacopeial compounds employing various analytical methods.

CO2. Apply technologies in Design and evaluation of different types of drug delivery system.

CO3. Understand the pre and post compression parameters and invitro kinetic studies

CO4. Work independently and communicate effectively in oral and written forms.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	2	3	2	-	1	-	-	-	-	-	3	-	-	-
CO2	2	3	2	-	1	-	-	-	-	-	3	-	-	-
CO3	2	3	1	-	1	-	-	-	-	-	3	-	-	-
CO4	-	-	-	-	-	-	3	3	-	-	3	-	-	-
Course Correlation Mapping	**2**	**3**	**2**	**-**	**1**	**-**	**3**	**3**	**-**	**-**	**3**	**-**	**-**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

EXPERIMENTAL LEARNING

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

II Semester

Course Code	Course Title	L	T	P	C
23PH201004	**MOLECULAR PHARMACEUTICS**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

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

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Demonstrate & analyze carrier mediated targeted DDS Pharmaceuticals.

CO2. Understand & analyze basics of vesicular DDS & its applications.

CO3. Understand the tools techniques & evolution of Naso-pulmonary DDS.

CO4. Understand the basics of gene-based therapeutics for inherited disorder insights.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	2	1	-	2	-	-	-	-	-	3	-	-	-
CO2	3	2	1	-	1	-	-	-	-	-	3	-	-	-
CO3	3	2	1	-	1	-	-	-	-	-	3	-	-	-
CO4	3	1	2	-	1	1	-	-	-	-	3	-	-	-
Course Correlation Mapping	3	2	1	-	1	1	-	-	-	-	**3**	-	-	-

Correlation Levels: **3: High;** **2: Medium;** **1: Low**

COURSE CONTENT

Module 1: TARGETED DRUG DELIVERY SYSTEMS ***(12 periods)***

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

Module 2: TARGETING METHODS ***(12 periods)***

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

Module 3: MICRO CAPSULES & MICRO SPHERES ***(12 periods)***

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

Module 4: PULMONARY DRUG DELIVERY SYSTEMS ***(12 periods)***

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

Module 5: GENE DRUG DELIVERY SYSTEMS ***(12 periods)***

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal

gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future

Total Periods: 60

RESOURCES

TEXT BOOKS:

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

VIDEO LECTURES

1. https://youtu.be/dB6Wws1iN_E
2. https://youtu.be/W_3tIgR9E9E
3. https://youtu.be/v2dKLHC0ep4

4. https://youtu.be/2sNLWcZ5xzM

WEB RESOURCES

1. https://gyansanchay.csjmu.ac.in/molecular-pharmaceutics-mph-201t/

Course Code	Course Title	L	T	P	C
23PH201005	**ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

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

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Understand the factors affecting GIT absorption of dosage forms.

CO2. Acquire knowledge on biopharmaceutical considerations in design and evaluation dosage forms by *invitro, in vivo*.

CO3. Understand the Pharmacokinetic & Pharmacodynamics parameters in design of pharmaceutical & biotechnological based DDS.

CO4. To critically evaluate biopharmaceutics studies involving drug product equivalency

CO5. The potential clinical pharmacokinetic problems and applications of basics of pharmacokinetics

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	1	3	-	-	-	-	-	-	-	3	-	2	-
CO2	3	1	3	-	-	-	-	-	-	-	3	2	2	-
CO3	3	2	2	-	-	-	-	-	-	-	3	-	2	-
CO4	3	1	-	-	1	-	-	-	-	-	-	2	-	-
CO5	1	2	2	-	-	-	-	-	-	-	-	3	-	-
Course Correlation Mapping	**3**	**2**	**2**	**-**	**1**	**-**	**-**	**-**	**-**	**-**	**3**	**2**	**2**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: DRUG ABSORPTION FROM GIT ***(12 periods)***

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: BIOPHARMACEUTICAL CONSIDERATIONS ***(12 periods)***

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

Module 3: PHARMACOKINETICS ***(12 periods)***

Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters

Module 4: PERFORMANCE OF DRUG PRODUCT ***(12 periods)***

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution

Module 5: PHARMACOKINETICS ***(12 periods)***

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

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996
12. Basic Pharmacokinetics, 1 st edition, Sunil S JambhekarandPhilip J Breen, pharmaceutical press, RPS Publishing,2009
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003

VIDEO LECTURES

1. https://youtu.be/pFPeor-SFHg
2. https://youtu.be/BJ1AUsEDjWo
3. https://youtu.be/lUph4upeqck
4. https://youtu.be/w63wdcmkhX4
5. https://youtu.be/tLCuehQvUOo

WEB RESOURCES

1. https://www.rgpv.ac.in/CDN/PubContent/Scheme/Industrial_Pharmacy_ II_Sem_Sy121021121349.pdf
2. https://vmrfdu.edu.in/files/Questions/Pharmacy/mpharm/ADVANCED%2 0BIOPHARMACEUTICS%20AND%20PHARMACOKINETICS.pdf

Course Code	Course Title	L	T	P	C
23PH201006	**COMPUTER AIDED DRUG DEVELOPMENT**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

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

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Understand the role of computer & application of Statistical tools in design of pharmaceutical.

CO2. Acquire skills in computational modeling of pharmacokinetics & pharmacodynamics of drug

CO3. Apply computer tools in formulation development clinical data management by ethical consideration computing.

CO4. Understand the fundamental & guidelines of herbal ingredients in design of cosmeceuticals.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	2	2	1	1	-	-	-	-	-	3	-	-	-
CO2	3	1	2	-	2	-	-	-	-	-	3	-	-	-
CO3	3	1	3	-	-	2	-	-	-	-	3	-	-	-
CO4	3	1	1	-	-	1	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**1**	**2**	**1**	**2**	**2**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: COMPUTERS IN PHARMACEUTICAL RESEARCH & DEVELOPMENT ***(12 periods)***

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling.
b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

Module 2: COMPUTATIONAL MODELING OF DRUG DISPOSITION ***(12 periods)***

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

Module 3: FORMULATION DEVELOPMENT ***(12 periods)***

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

Module 4: BIOPHARMACEUTICAL CHARACTERIZATION ***(12 periods)***

a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations
b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Module 5: AI & ROBOTICS ***(12 periods)***

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

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996

VIDEO LECTURES

1. https://youtu.be/82NbdxLl23E
2. https://youtu.be/RCGJ1sh2xK4
3. https://youtu.be/1eG-ePzRB0w
4. https://youtu.be/Acx_Hcvh2g8

WEB RESOURCES

1. https://core.ac.uk/download/pdf/230739217.pdf

Course Code	Course Title	L	T	P	C
23PH201007	**COSMETICS AND COSMECEUTICALS**	**4**	**-**	**-**	**4**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

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

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Understand the regulatory related cosmeceuticals.

CO2. Understand the biological aseptic & design cosmeceutical.

CO3. Able to apply key building blocks to design cosmeceutical.

CO4. Understand the fundamental & guidelines of herbal ingredients in design of cosmeceuticals.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	-	1	-	-	3	-	-	-	-	3	-	-	-
CO2	3	2	2	-	2	-	-	-	-	-	3	-	-	-
CO3	3	1	3	-	1	-	-	-	-	-	3	-	-	-
CO4	3	1	2	-	1	2	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**1**	**2**	**-**	**1**	**3**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: COSMETICS – REGULATORY ASPECTS ***(12 periods)***

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

Module 2: COSMETICS – BIOLOGICAL ASPECTS ***(12 periods)***

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

Module 3: FORMULATION BUILDING BLOCKS ***(12 periods)***

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane

Module 4: DESIGN OF COSMECEUTICALS ***(12 periods)***

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

Module 5: HERBAL COSMETICS ***(12 periods)***

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

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Harry's Cosmeticology. 8th edition
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics – Formulation, Manufacture and quality control, PP. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue
6. CTFA directory

VIDEO LECTURES

1. https://youtu.be/v_4wGSbp6lA
2. https://youtu.be/6evUD1hI6Do
3. https://youtu.be/ajvfJnGv5Uw
4. https://youtu.be/bdab20osNYc

WEB RESOURCES

1. https://gyansanchay.csjmu.ac.in/wp-content/ uploads/ 2022/ 04/ Cosmetics -and- Cosmoceuticcals-introduction.pdf

Course Code	Course Title	L	T	P	C
23PH205002	**PHARMACEUTICS PRACTICAL-II**	**-**	**-**	**12**	**6**

Pre-Requisite -

Anti-Requisite -

Co-Requisite -

COURSE DESCRIPTION: Course designed to impart knowledge and skills in the preparation and evaluation of novel drug delivery systems and cosmeceuticals.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

CO1. Work independently in design & evaluation of micro particles.

CO2. Develop & analyze (characterize) vesicular DDS

CO3. Apply practical skills to improve dissolution profiles of drugs

CO4. Analyze invitro, in vivo pharmacokinetic parameter of drugs using software

CO5. Design & analyze formulation & biopharmaceutical parameter by employing software system.

CO6. Design & analyze herbal & other cosmeceuticals.

CO7. Work independently & communicate effectively in oral & written forms

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes										Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
CO1	3	2	2	-	1	1	-	-	-	-	3	-	-	-
CO2	3	2	2	-	1	1	-	-	-	-	3	-	-	-
CO3	3	3	2	-	1	1	-	-	-	-	3	-	-	-
CO4	3	1	3	-	1	1	-	-	-	-	3	-	-	-
CO5	3	2	3	-	1	1	-	-	-	-	3	-	-	-
CO6	3	2	2	-	1	2	-	-	-	-	3	-	-	-
CO7	-	-	-	-	-	-	3	3	-	-	3	-	-	-
Course Correlation Mapping	**3**	**2**	**2**	**-**	**1**	**2**	**3**	**3**	**-**	**-**	**3**	**-**	**-**	**-**

Correlation Levels: 3: High; 2: Medium; 1: Low

EXPERIMENTAL LEARNING

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 spherules
5. Formulation and evaluation of liposomes/niosomes
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 WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff