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 Pharmaceutical Analysis

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. (Pharmaceutical Analysis) 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. (Pharmaceutical Analysis) 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. (Pharmaceutical Analysis), the graduates will be able to:

PSO1: Emphasize hyphenated spectroscopic and chromatographic techniques for the identification, characterization and quantification of pharmaceuticals, food products, herbals and cosmetics

PSO2: Acquaint with the science of impurity detection in pharmaceutical formulations, as well as profiling, stability testing, assays, and protocol development.

PSO3: Comprehend qualifications, installation, operational, maintenance and validation of analytical and lab equipment in accordance with ICH, regulatory guidelines

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-curricularactivities is dependent upon the quantum of work expected to be put in by the student for eachof 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></td><td></td><td colspan="2"></td><td></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></td><td></td><td colspan="2"></td><td></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></td><td></td><td colspan="2"></td><td></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 allowed to appear for examinations of the remaining courses of that semester. The candidate is also

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
		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 Controller of Examinations, or any person on duty in or outside the examination hall or any of his relations,	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:	
	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. (Pharmaceutical Analysis)

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.	23PA201002	Advanced Pharmaceutical Analysis	4	-	-	4	4	25	75	100
3.	23PA201003	Pharmaceutical Validation	4	-	-	4	4	25	75	100
4.	23PA201004	Food Analysis	4	-	-	4	4	25	75	100
5.	23PA205001	Pharmaceutical Analysis Practical-I			12	12	6	50	100	150
6.	23PA211001	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.	23PA201005	Advanced Instrumental Analysis	4	-	-	4	4	25	75	100
2.	23PA201006	Modern Bio-Analytical Techniques	4	-	-	4	4	25	75	100
3.	23PA201007	Quality Control and Quality Assurance	4	-	-	4	4	25	75	100
4.	23PA201008	Herbal and Cosmetic Analysis	4	-	-	4	4	25	75	100
5.	23PA205002	Pharmaceutical Analysis Practical-II			12	12	6	50	100	150
6.	23PA211002	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.	23PA211003	Journal Club-I	-	-	-	-	1	25		25
3.	23PA211004	Proposal Presentation	-	-	-	-	2	50		50
4.	23PA209001	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.	23PA211005	Journal Club-II	-	-	-	-	1	25		25
2.	23PA211006	Dissertation Presentation	-	-	-	-	3	75		75
3.	23PA210001	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 ***(12 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. **Spectro flourimetry:** 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 ***(12 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 ***(12 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 ***(12 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 ***(12 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

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
23PA201002	**ADVANCED PHARMACEUTICAL ANALYSIS**	**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 the elemental impurities and their degradation characterization of pharmaceuticals as per ICH guidelines

CO2. Understand the concepts of Impurity profiling and stability studies & its quantification protocols as per ICH guidelines.

CO3. Apply appropriate tools to understand the concepts of Stability studies as per WHO & ICH guidelines

CO4. Demonstrate the essentials of biological tests and assays of various vaccines

CO5. Analyze the basics of Immunoassay methods and their applications

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	-	-	-	-	-	-	3	-	-	1
CO2	3	2	-	1	-	-	-	-	-	-	3	-	-	1
CO3	3	2	-	1	-	-	-	-	-	-	3	-	-	1
CO4	3	2	-	1	-	-	-	-	-	-	3	-	-	1
CO5	3	2	-	1	-	-	-	-	-	-	3	-	-	1
Course Correlation Mapping	**3**	**2**	**-**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**1**

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

COURSE CONTENT

Module 1: IMPURITY AND STABILITY STUDIES ***(11 Periods)***

a. Impurity and Stability Studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines
b. Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
c. Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

Module 2: ELEMENTAL IMPURITIES & STABILITY TESTING ***(11 Periods)***

a. Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis
b. Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

Module 3: IMPURITY PROFILING & DEGRADANT CHARACTERIZATION ***(11 Periods)***

Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

Module 4: STABILITY TESTING OF PHYTOPHARMACEUTICALS ***(11 Periods)***

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity

Module 5: BIOLOGICAL TESTING ***(11 Periods)***

a. Adsorbed Tetanus vaccine
b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine
d. Rabies vaccine
e. Tetanus Anti toxin
f. Tetanus Anti serum
g. Oxytocin
h. Heparin sodium IP
i. Antivenom.
j. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

Module 6: IMMUNOASSAYS ***(05 Periods)***

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5 th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London
14. ICH Guidelines for impurity profiles and stability studies

VIDEO LECTURES:

1. https://mypharmacareer.wordpress.com/
2. https://www.instamojo.com/ThingsbyAmi...
3. https://bit.ly/2XlDmtw

WEB RESOURCES:

1. https://mypharmacareer.wordpress.com
2. https://www.instamojo.com/ThingsbyAmi...

COURSE CORE

Course Code	Course Title	L	T	P	C
23PA201003	**PHARMACEUTICAL VALIDATION**	**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 the fundamental concepts of Qualification &Validation of Manufacturing, Analytical and Laboratory equipment's

CO2. Analyze the standards of various laboratory glassware and analytical instruments.

CO3. Attain knowledge on, equipment's and facilities for Validation of Utility systems & Design and development of Cleaning protocols

CO4. Acquire the Knowledge on Validation of various analytical method as per standards.

CO5. Demonstrate the fundamental concepts of Intellectual Property rights with reference to patents, transfer technology

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	-	-	-
CO2	3	2	-	-	-	-	-	-	-	-	3	-	-	-
CO3	3	2	-	-	-	-	-	-	-	-	3	-	-	-
CO4	3	2	-	-	-	-	-	-	-	-	3	-	-	-
CO5	3	2	-	-	-		-	-	-	-	-	-	-	-
Course Correlation Mapping	**3**	**2**	-	-	-	**-**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

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

COURSE CONTENT

Module 1: INTRODUCTION TO VALIDATION ***(12 Periods)***

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

Module 2: QUALIFICATION OF ANALYTICAL INSTRUMENTS ***(12 Periods)***

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette

Module 3: VALIDATION OF UTILITY SYSTEMS ***(12 Periods)***

Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place

Module 4: VALIDATION OF ANALYTICAL METHOD ***(12 Periods)***

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. 12 Hrs 12 Hrs 104 Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5

Module 5: GENERAL PRINCIPLES OF INTELLECTUAL PROPERTY ***(12 Periods)***

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker)
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

VIDEO LECTURES

1. https://go.pharmaguideline.com/youtube
2. https://m.facebook.com/groups/9339422...
3. https://play.google.com/store/apps/de...

WEB RESOURCES:

1. https://play.google.com/store/apps/de...
2. https://go.pharmaguideline.com/youtube

Course Code	Course Title	L	T	P	C
23PA201004	**FOOD ANALYSIS**	**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. Acquire knowledge on chemistry, processing and analysis of bio-molecules such as carbohydrates, proteins & Lipids

CO2. Understand classification, processing and analysis of Lipids and vitamins

CO3. Acquire knowledge on analysis of food additives and detection of dyes in industry.

CO4. Acquire knowledge on analysis of milk and fermentation products

CO5. Understand the analysis of Pesticides in accordance with the standards of Legislation regulations of food products

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	-	-	-	-	-	-	-	-	3	-	-	-
CO2	3	3	-	-	-	-	-	-	-	-	3	-	-	-
CO3	3	3	-	1	-	-	-	-	-	-	3	-	-	-
CO4	3	3	-	-	-	-	-	-	-	-	3	-	-	-
CO5	3	3	-	-	-	-	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**3**	**-**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

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

COURSE CONTENT

Module 1: CARBOHYDRATES & PROTEINS ***(12 Periods)***

Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

Module 2: LIPIDS & VITAMINS ***(12 Periods)***

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

Module 3: FOOD ADDITIVES ***(12 Periods)***

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic 12 Hrs 106 dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

Module 4: MILK & FERMENTATION PRODUCTS ***(12 Periods)***

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

Analysis of fermentation products like wine, spirits, beer and vinegar

Module 5: PESTICIDE ANALYSIS & LEGISLATION REGULATIONS ***(12 Periods)***

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 197
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 199
4. Analysis of Food constituents – Multon, Wiley VC
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 20

VIDEO LECTURES

1. Indian Pharma Guide
2. https://www.findyouranswers.co/results/your_search
3. https://www.allwealthinfo.com/best-results/now

WEB RESOURCES

1. https://www.findyouranswers.co/results/your_search
2. Indian Pharma Guide

COURSE CORE

Course Code	Course Title	L	T	P	C
23PA205001	**PHARMACEUTICAL ANALYSIS 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. Perform and analyze the Pharmacopeial compounds & their formulations by absorption & emission spectroscopic methods

CO2. Accomplish knowledge on calibration of analytical instruments & quantitative determination of functional groups, biomolecules & pharmaceutical additives.

CO3. Work as an individual and as a member of a team to solve problems with effective communications

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	-	-	-	-	-	-	-	3	-	-	-
CO2	3	3	1	-	-	-	-	-	-	-	3	-	-	-
CO3	3	3	1	-	-	-	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**3**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

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

COURSE CONTENT

EXPERIMENTAL LEARNING

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. Assay of official compounds by different titrations
7. Assay of official compounds by instrumental techniques.
8. Estimation of sodium/potassium by flame photometry
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glassware
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

II Semester

Course Code	Course Title	L	T	P	C
23PA201005	**ADVANCED INSTRUMENTAL ANALYSIS**	**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 the fundamental concepts of HPLC & its trouble shooting, preparative and chiral method analysis of pharmaceuticals & its applications.

CO2. Demonstrate the fundamental concepts, derivatization techniques of diverse chromatographic techniques & their pharmaceutical applications.

CO3. Understand the basic concepts, method development and their pharmaceutical applications of Super critical fluid chromatography & capillary electrophoresis techniques.

CO4. Demonstrate the fundamental concepts, interpretation of mass spectrum pattern & its pharmaceutical applications.

CO5. Comprehend the fundamental concepts, interpretation of diverse NMR spectroscopic techniques and their pharmaceutical applications

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	-	-	-	-	-	-	3	-	-	-
CO2	3	2	-	1	-	-	-	-	-	-	3	-	-	-
CO3	3	2	-	1	-	-	-	-	-	-	3	-	-	-
CO4	3	2	-	1	-	-	-	-	-	-	3	-	-	-
CO5	3	2	-	1	-	-	-	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**2**	**-**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

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

COURSE CONTENT

Module 1: HIGH PERFORMANCE LIQUID CHROMATOGRAPHY *(12 Periods)*

HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC

Module 2: BIOCHROMATOGRAPHY *(12 Periods)*

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications

Module 3: SUPER CRITICAL FLUID CHROMATOGRAPHY *(12 Periods)*

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation

Module 4: ADVANCED MASS SPECTROMETRY *(12 Periods)*

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap

Module 5: ADVANCED NMR SPECTROSCOPY *(12 Periods)*

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 with reference to 13CNMR: Spin-spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley &
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
3. Instrumental methods of analysis – Willards, 7 th edition, CBS publishers
4. Organic Spectroscopy - William Kemp, 3 rd edition, ELBS, 1991
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3 rd Edition, CBS Publishers, New Delhi, 1997
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition

VIDEO LECTURES

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

WEB RESOURCES

1. https://www.youtube.com/channel/UCU91...
2. https://amzn.to/2XacNUG

Course Code	Course Title	L	T	P	C
23PA201006	**MODERN BIO-ANALYTICAL TECHNIQUES**	**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. Comprehend the concepts of drugs and metabolites extraction methods and Bioanalytical method validation as per Standard procedures.

CO2. Demonstrate the fundamental concepts, drug bioavalibity and its effecting factors & experimental methods in In-Vitro& In-Vivo methods.

CO3. Understand the fundamental concepts of Pharmacokinetic and Toxicokinetic studies, their evaluation & bioactivity screening methods by LC-MS method.

CO4. Understand the basic concepts of different types of cell culture techniques, isolation, assay methods and their applications

CO5. Acquire knowledge on metabolite identification and clinical significance of bioavailability and bioequivalence studies

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	-	-	-	-	1	-	-	-	3	-	-	-
CO2	3	1	-	-	-	-	1	-	-	-	3	-	-	-
CO3	3	2	-	-	-	-	1	-	-	-	3	-	-	-
CO4	3	2	**-**	**-**	**-**	**-**	1	**-**	**-**	**-**	3	-	-	-
CO5	3	2	**-**	**-**	**-**	**-**	1	**-**	**-**	**-**	3	-	-	-
Course Correlation Mapping	**3**	**1**	**-**	**-**	**-**	**-**	**1**	**-**	**-**	**-**	**3**	-	-	-

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

COURSE CONTENT

Module 1: EXTRACTION OF DRUGS FROM BIOLOGICAL MATRICES ***(12 Periods)***

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines

Module 2: BIOPHARMACEUTICAL CONSIDERATION ***(12 Periods)***

Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods

Module 3: PHARMACOKINETICS & TOXICOKINETICS ***(12 Periods)***

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

Module 4: CELL CULTURE LAB ***(12 Periods)***

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of 12 Hrs 111 cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry

Module 5: HANDLING OF METABOLITES & BIOEQUIVALENCE STUDIES ***(12 Periods)***

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies

Total Periods: 60

RESOURCES:

TEXT BOOKS:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2 nd Edition. CRC Press, Newyork. 1995
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5 th edition, Eastern press, Bangalore, 1998
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2 nd Edition, Wiley – Interscience Publications, 1961
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2 nd Edition, John Wiley & Sons, New Jercy. USA
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2 nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989
10. ICH, USFDA & CDSCO Guidelines

VIDEO LECTURES

1. https://share.graphyapp.co/qVZ5
2. https://www.youtube.com/channel/UCU91...
3. https://amzn.to/2XacNUG
4. https://www.amazon.in/shop/Dr.Puspend...

WEB RESOURCES

1. https://amzn.to/2XacNUG
2. https://www.youtube.com/channel/UCU91..

Course Code	Course Title	L	T	P	C
23PA201007	**QUALITY CONTROL AND QUALITY ASSURANCE**	**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. Comprehend the concepts of evaluation of Quality control & Quality assurance, GMP & GLP standard guidelines.

CO2. Acquire knowledge on cGMP standard guidelines according Schedule M

CO3. Attain knowledge on analysis of specification of quality control of pharmaceuticals according their pharmacopoeias.

CO4. Acquire the Knowledge on basic principles; stand operating procedures for documentation in pharmaceutical industry.

CO5. Demonstrate the fundamental concepts of diverse steps in manufacturing operation and its control.

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	-	-	-	3	-	-	-
CO2	3	2	-	-	-	-	1	-	-	-	3	-	-	-
CO3	3	2	-	-	-	-	1	-	-	-	3	-	-	-
CO4	3	2	-	-	-	-	1	-	-	-	3	-	-	-
CO5	3	2	-	-	-	-	1	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**2**	**-**	**-**	**-**	**-**	**1**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

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

COURSE CONTENT

Module 1: EVOLUTION OF QUALITY CONTROL ***(12 periods)***

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation

Module 2: CGMP GUIDELINES ***(12 periods)***

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guideline

Module 3: IN PROCESS QUALITY CONTROL ***(12 periods)***

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3). Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials

Module 4: DOCUMENTATION IN PHARMACEUTICAL INDUSTRY ***(12 periods)***

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data

Module 5: MANUFACTURING OPERATIONS AND CONTROL ***(12 periods)***

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2 nd edition, WHO Publications, 1999
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3 rd edition, WHO, Geneva, 2005
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4 th edition, Susmit Publishers, 2006
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008

VIDEO LECTURES

1. https://kclpharmacy.com/
2. https://www.facebook.com/anurag.jaisw...
   https://www.pharma-revolution.com/
3. https://www.facebook.com/pharmarevolu..
4. https://share.graphyapp.co/qVZ5

WEB RESOURCES

1. https://www.youtube.com/channel/UCU91..
2. https://www.youtube.com/channel/UCU91..

Course Code	Course Title	L	T	P	C
23PA201008	**HERBAL AND COSMETIC ANALYSIS**	**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. Comprehend the regulations of herbal remedies, validation of herbal therapies& herbal drug standardization as per WHO & AYUSH guidelines.

CO2. Acquire knowledge on adulteration and deterioration of herbal drugs & identification of phototoxin and microbial contamination in herbal formulations.

CO3. Attain knowledge on testing of natural products and drugs. Quality assessment of herbal drugs by WHO & AYUSH guidelines.

CO4. Acquire the Knowledge safety monitoring of herbal drugs by WHO and AYUSH guidelines and challenges monitoring in herbal medicines.

CO5. Demonstrate the fundamental concepts of evaluation of cosmetic products as per Indian standard specifications.

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	-	-	-	3	-	-	-
CO2	3	2	-	-	-	**-**	1	-	-	-	3	-	-	-
CO3	3	2	-	-	-	**-**	1	-	-	-	3	-	-	-
CO4	3	2	-	-	-	**-**	1	-	-	-	3	-	-	-
CO5	3	2	-	-	-	**-**	1	-	-	-	3	-	-	-
Course Correlation Mapping	**3**	**2**	**-**	**-**	**-**	**-**	**1**	**-**	**-**	**-**	**3**	**-**	**-**	**-**

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

COURSE CONTENT

Module 1: HERBAL REMEDIES ***(12 periods)***

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines

Module 2: ADULTERATION AND DETERIORATION ***(12 periods)***

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol

Module 3: NATURAL DRUGS ***(12 periods)***

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic 12 Hrs 116 Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

Module 4: HERBAL DRUG- DRUG INTERACTION ***(12 periods)***

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

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

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Stand

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4 th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition

VIDEO LECTURES

1. https://kclpharmacy.com/
2. https://share.graphyapp.co/qVZ5
3. https://amzn.to/2JQNwvI
4. https://share.graphyapp.co/qVZ5

WEB RESOURCES

1. https://www.youtube.com/channel/UCU91...
2. https://amzn.to/2XacNUG

Course Code	Course Title	L	T	P	C
23PA205002	**PHARMACEUTICAL ANALYSIS 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. Perform and analyze the Pharmacopeial compounds & their formulations by absorption & emission spectroscopic methods.

CO2. Accomplish knowledge on calibration of analytical instruments & quantitative determination of functional groups, biomolecules & pharmaceutical additives

CO3. Work as an individual and as a member of a team to solve problems with effective communications

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	-	-	-
Course Correlation Mapping	**3**	**3**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**2**	**-**	**-**	**-**

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

EXPERIMENTAL LEARNING

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

RESOURCES

VIDEO LECTURES

1. https://drive.google.com/file/d/1c9VR...
2. https://share.graphyapp.co/qVZ5

WEB RESOURCES

1. https://share.graphyapp.co/qVZ5