Sri Padmavathi School of Pharmacy (Autonomous)

Mohan Gardens, Vaishnavi Nagar, Tiruchanoor, Andhra Pradesh,India-517 503
Phone: 76619 76616 Fax: 0877 2237732 website: www.spsp.ac.in

(Conferred Autonomous status from the academic year 2024-25)
Accorded under Sections 2 (f) and 12 (B) of UGC act 1956 and Accredited by National Board of Accreditation (NBA) for UG and National Assessment & Accreditation Council (NAAC),Approved by PCI and AICTE, New Delhi

Academic Regulations-MR24
Program Structure
&
Syllabus

Effective from AY 2024-25 onwards

Master of Pharmacy
Pharmaceutical Analysis

Awarding University
Jawaharlal Nehru Technological University Anantapur
JNTUA

Introduction to the Document

The regulations published in this document are official guidelines by the Board of studies (BoS) and Academic council of Sri Padmavathi School of Pharmacy (SPSP) - Autonomous, Andhra Pradesh. The document is a fusion product based on recommendations and guidelines stipulated for syllabus structure by UGC, AICTE, PCI, New Delhi.

- Academic regulations stipulated by Jawaharlal Nehru Technological University Anantapur (JNTUA), Ananthapuramu, Andhra Pradesh.
- Experts' opinion from the Board of Studies, Academic Council constituting approved Advisory boards members includes both academicians and researchers from reputed organizations at national and international levels.
- Suggestions and inputs from members of academic council and Board of studies.
- Recommendations based on feedback from alumni, employers, faculty, students, parents and other experts from allied area.
- This academic regulations, Program structure & Syllabus document has been prepared to ensure quality system in teaching and learning process, examination, assessment, and functioning of other academic related matters to the satisfaction of stakeholders, such as students, parents, alumni, employers, faculty, etc. This document provides core principles of academic regulations duly approved by academic council and board of studies of this institution. The Implementation of these academic regulations shall lead to be considered in the institute and thereby enrich the quality of education and research in the field of pharmaceutical sciences. The guidelines shall aid the transparency and accountability in the administration set up. The list of objectives for implementing academic regulations and course structure through these guidelines are listed below,
    - To improve the academic regulations and course structure.
    - To strengthen the Industry-Institute interaction.
    - To comply with rules and regulations of regulatory bodies like U G C , JNTUA, PCI, AICTE etc.,
    - To meet the requirements of accreditation council and board.
    - To enhance the quality of teaching-learning process and assessments.
    - To provide career support programs, training for enhancing quality in placements and higher education.
    - To place improved systems for feedback, self-appraisal of faculty and staff.
    - To create bench marking with other institutes of repute.

Preamble

The regulations stated herein below shall be called as a document of "Academic regulations, Program structure & Syllabus for M. Pharm – Pharmaceutical Analysis " Sri Padmavathi School of Pharmacy (SPSP) - Autonomous, Andhra Pradesh.

These regulations shall be in force from the batch admitted from 2024 -2025 by the date of ratification by the Academic council and Board of studies (BoS) of the institute.

In the event of any doubt about the interpretation of these regulations, the matter shall be referred to Board of studies (BoS) and Academic council and their decision shall be final.

The Board of studies (BoS) and Academic council shall have the authority to modify, amend and repeal any of the provisions of these regulations from time to time.

Definitions

i. "College" means "Sri Padmavathi School of Pharmacy (SPSP) - Autonomous, Andhra Pradesh".

ii. "Student" means a candidate who has taken admission into B. Pharm course of this college as per the guidelines stipulated from time to time by the regulations of State Government of Andhra Pradesh and the Government of India for admissions into various courses of study and the affiliating university, i.e., Jawaharlal Nehru Technological University, Anantapur (JNTUA), Ananthapuramu, Andhra Pradesh.

iii. "Academic Council" means the Academic council constituted as per the guidelines of UGC.

iv. "Board of Studies" means Board of Studies constituted in each department as per the guidelines of UGC.

v. "Principal" means the Head of the institution

vi. "Head of the Department" means the Head of an Academic Department of the College.

vii. "Faculty member" means the teacher (Assistant/Associate/Professor) working on regular or ad-hoc basis in any of the Academic Departments of the College.

viii. "Program" means a candidate who has chosen to avail degree of B. Pharm of this college as per the marks/ rank awarded by the National/ University/ State common entrance tests, India.

ix. "Course" individual subjects described with content for instructions to the students.

x. "Assessment" means evaluation process for the outcome and grading in term of the marks.

xi. "Credit" means a weight to the time requirements of the academic course in the institute.

VISION OF THE INSTITUTE

To promote holistic learning, nurture ethically strong and highly competent Pharmacy graduates to serve the global healthcare system.

MISSION OF THE INSTITUTE

- ✓ **M1**. To provide innovative and contemporary educational experiences of the highest quality.
- ✓ **M2**. To instill ethics, sense of professionalism, communication and leadership skills.
- ✓ **M3**. To promote and nurture the research and scholarly activities.
- ✓ **M4**. To foster entrepreneurship and life-long learning.

Program Outcomes (POs)

1. PO1: Knowledge in Domain
   Possess adequate knowledge and comprehension of basic and core areas of pharmaceutical analysis, quality assurance and quality control.
2. PO2: Planning Abilities:
   Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
3. PO3: Problem Analysis
   Develop ability for in-depth analytical and critical thinking in order to identify and solve the issues related to

identification, estimation and structural elucidation of pharmaceutical compounds.

4. PO4: Modern Tool Usage

   Learn, select and apply appropriate methods & procedures, resources and computing tools with an understanding of the limitations in analytical method development.

5. PO5: Leadership Skills

   Demonstrate the ability to function effectively as an individual and as a member or leader in diverse teams in various areas of pharmaceutical testing.

6. PO6: Professional Identity

   Understand, analyze and communicate the value of their professional roles (e.g. pharmaceutical analysts, QA setting, QC setting etc.)

7. PO7: Ethics

   Apply ethical principles and professional ethics and norms in testing and reporting of analytical results.

8. PO8: Communication

   Able to develop written and oral communication skills that contribute effectively within the pharmaceutical industry and in the community.

9. PO9: Pharmacist and Society

   Develop an understanding for the need of pharmaceutical analysis and role of analyst in giving quality life to people in society.

10. PO10: Environment and Sustainability

    Understand the impact of the chemical and reagents used in pharmaceutical testing in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

11. PO11: Life-long Learning

    Recognize the need for, and have the preparation and ability to engage in independent and lifelong learning in the broadest context of technological change.

Academic Regulations of M.Pharmacy Pharmaceutical Analysis (Full Time) Program – MR-24

(Effective for the students admitted into I year from the Academic Year 2024-25 and onwards)

Sri Padmavathi School of Pharmacy (SPSP)-Autonomous, offers **Two** Years (**Four** Semesters) full-time Master of Pharmacy (M.Pharm) Post Graduate Degree program, under Choice Based Credit System (CBCS) with three different specializations.

The Jawaharlal Nehru Technological University Anantapur shall confer M.Pharm. degree on candidates who are admitted to the program and fulfill all the requirements for the award of the degree.

1. Award of the M.Pharm. Degree

A student will be declared eligible for the award of the M.Pharm. degree if he/she fulfils the following:

1.1 Pursues a course of study for not less than two academic years and not more than four academic years.

1.2 Registers for 95 credits and secures all 95 credits.

2. Students, who fail to fulfil all the academic requirements for the award of the degree within four academic years from the year of their admission, shall forfeit their seat in M.Pharm. course and their admission stands cancelled.

3. **Program of Study:**

The following M.Pharm. specializations are offered by the college:

S.No.	Discipline	Name of the Specialization	Code
1	Master of Pharmacy	Pharmacology	MPL
2		Pharmaceutics	MPH
3		Pharmaceutical Analysis	MPA

4. **Eligibility for Admissions**:

4.1 Admission to the M.Pharm. program shall be made subject to the eligibility, qualifications and specialization prescribed by the A.P. State Government/University for each program, from time to time.

4.2 Admissions shall be made on the basis of either the merit rank or Percentile obtained by the qualified student in the relevant qualifying GPAT Examination / the merit rank obtained by the qualified student in an entrance test conducted by A.P. State Government (APPGECET) for M.Pharm. programs/an entrance test conducted by university/ on the basis of any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.

5. **Program related terms:**

5.1 ***Credit:*** A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (Lecture/Tutorial) or two hours of practical work/field work per week.

Credit definition:

1 Hr. Lecture (L) per week	1 credit
1 Hr. Tutorial (T) per week	1 credit
1 Hr. Practical (P) per week	0.5 credit

5.2 ***Academic Year:*** Two consecutive (one odd + one even) semesters constitute one academic year.

5.3 ***Choice Based Credit System (CBCS):*** The CBCS provides choice for students to select from the prescribed courses.

6. **Program Pattern:**

6.1 Total duration of the of M.Pharm. program is two academic years

6.2 Each academic year of study is divided into two semesters.

6.3 Each Semester shall be of 22 weeks duration (inclusive of Examinations), with a minimum of 90 instructional days per semester.

6.4 The student shall not take more than four academic years to fulfill all the academic requirements for the award of M.Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M.Pharm. program.

6.5 The medium of instruction of the program (including examinations and project reports) will be in English only.

6.6 All subjects/courses offered for the M.Pharm. program are broadly classified as follows:

S.No.	Broad Course Classification	Course Category	Description
1.	Core Courses	Foundational & Professional Core Courses (PC)	Includes subjects related to the parent discipline
2.	Elective Courses	Electives	Includes elective subjects related to the parent discipline/inter-disciplinary subjects or subjects in an area outside the parent discipline which are of importance in the context of special skill development
3.	Research	Research methodology & IPR	To understand importance and process of creation of patents through research
		Seminar	Ensures preparedness of students to undertake major projects/Dissertation, based on core contents related to specialization
		Cocurricular Activities/Journal Club	Attending conferences, scientific presentations and other scholarly activities
		Dissertation	Major Project
4.	Audit Courses	Mandatory noncredit courses	Covering subjects of developing desired attitude among the learners is on the line of initiatives such as Unnat Bharat Abhiyan, Yoga, Value education etc.

6.7 The college shall take measures to implement Virtual Labs (https://www.vlab.co.in) which provide remote access to labs in various disciplines of science and will help student in learning basic and advanced concept through remote experimentation. Student shall be made to work on virtual lab experiments during the regular labs.

6.8 A faculty advisor/mentor shall be assigned to each specialization to advise students on the program, its Course Structure and Curriculum, Choice of Courses, based on his competence, progress, pre-requisites and interest.

6.9 Preferably 25% course work for the theory courses in every semester shall be conducted in the blended mode of learning.

7. Attendance Requirements:

7.1 A student shall be eligible to appear for the external examinations if he/she acquires i) a minimum of 50% attendance in each course and ii) 75% of attendance in aggregate of all the courses.

7.2 Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester may be granted by the College Academic Committee.

7.3 Condonation of shortage of attendance shall be granted only on genuine and valid reasons on representation by the candidate with supporting evidence

7.4 Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examination of that class.

7.5 A stipulated fee shall be payable towards condonation of shortage of attendance.

7.6 A student will not be promoted to the next semester unless he satisfies the attendance requirements of the present semester. They may seek re-admission into that semester when offered next.

7.7 If any candidate fulfils the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

7.8 If the learning is carried out in blended mode (both offline & online), then the total attendance of the student shall be calculated considering the offline and online attendance of the student.

8. Evaluation – Distribution and Weightage of Marks:

The performance of a student in each semester shall be evaluated subject - wise (irrespective of credits assigned), for a maximum of 100 marks for theory and 100 marks for practical, based on Internal Evaluation and End Semester Examination.

8.1 There shall be five units in each of the theory subjects. For the theory subjects 60 marks will be for the End Examination and 40 marks will be for Internal Evaluation.

8.2 Two Internal Examinations shall be conducted for 30 marks each, one in the middle of the Semester and the other immediately after the completion of instruction. First mid examination shall be conducted for I & II units of the syllabus and second mid examination for III, IV & V units. Each mid exam shall be conducted for a total duration of 120 minutes with 3 questions (without choice) each question for 10 marks. Final Internal marks for a total of 30

marks shall be arrived at by considering the marks secured by the student in both the internal examinations with 80% weightage to the better internal exam and 20% to the other. There shall be an online examination (TWO) conducted during the respective mid examinations by the college for the remaining 10 marks with 20 objective questions.

8.3 The following pattern shall be followed in the End Examination:

i. Five questions shall be set from each of the five units with either/or type for 12 marks each.

ii. All the questions have to be answered compulsorily. iii. Each question may consist of one, two or more bits.

8.4 For practical subjects, 60 marks shall be for the End Semester Examinations and 40 marks will be for internal evaluation based on the day-to-day performance.

The internal evaluation based on the day-to-day work-10 marks, record- 10 marks and the remaining 20 marks to be awarded by conducting an internal laboratory test. The end examination shall be conducted by the examiners, with a breakup mark of Procedure-10, Experimentation-25, Results-10, Viva- voce-15.

8.5 There shall be a **Seminar/Assignment** for internal evaluation of 100 marks. A student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Project Review Committee consisting of Head of the Department, supervisor/mentor and two other faculty members of the department. The student has to secure a minimum of 50% of marks, to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when supplementary examinations are conducted. The seminar shall be conducted anytime during the semester as per the convenience of the Project Review Committee and students. There shall be no external examination for Technical Seminar.

8.6 For Teaching Practice/Assignments there will be an internal evaluation of 100 marks. A candidate has to secure a minimum of 50% to be declared successful. Student has to teach 10 Hours in his/her interesting subject/subjects in the entire III Semester instruction period for his juniors at PG level or Undergraduate students who are available on the campus. For each teaching hour maximum of 10 marks are allotted. The assessment will be made by the faculty allotted by the HoD.

8.7 There shall be Mandatory Audit courses for zero credits. There is no external examination for audit courses. However, attendance shall be considered while calculating aggregate attendance and student shall be declared to have passed the mandatory course only when he/she secures 50% or more in the internal examinations. In case, the student fails, a re-examination shall be conducted for failed candidates for 40 marks every six months/semester satisfying the conditions mentioned in item 1 & 2 of the regulations.

8.8 There shall be Comprehensive Viva–Voce in III semester. This will test the student's learning and understanding during the course of their specialization. The Comprehensive viva-voce will be conducted by the committee consisting of Head of the Department and two faculty members related to the specialization. The Comprehensive Viva-Voce shall be evaluated for 100 marks by the committee. There are no internal marks for the Comprehensive Viva-Voce. A student shall acquire 2 credits assigned to the Comprehensive Viva–voce when he/she secures 50% or more marks for the total of 100 marks. In case, if a student fails in Comprehensive Viva–voce he/she shall reappear as and when III semester supplementary examinations are conducted.

8.9 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum

aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

8.10 In case the candidate does not secure the minimum academic requirement in any of the subjects he/she has to reappear for the Semester Examination either supplementary or regular in that subject or repeat the course when next offered or do any other specified subject as may be required.

8.11 The laboratory records and mid semester test papers shall be preserved for a minimum of 3 years in the respective institutions as per the University norms and shall be produced to the Committees of the University as and when the same are asked for.

9. **Credit Transfer Policy**

As per University Grants Commission (Credit Framework for Online Learning Courses through SWAYAM) Regulation, 2016, the college shall allow up to a maximum of 40% of the total courses being offered in a particular Program in a semester through the Online Learning courses through SWAYAM.

9.1 The college shall offer credit mobility for MOOCs and give the equivalent credit weightage to the students for the credits earned through online learning courses through SWAYAM platform.

9.2 The online learning courses available on the SWAYAM platform will be considered for credit transfer. SWAYAM course credits are as specified in the platform

9.3 Student registration for the MOOCs shall be only through the institution, it is mandatory for the student to share necessary information with the institution

9.4 The institution shall select the courses to be permitted for credit transfer through SWAYAM. However, while selecting courses in the online platform institution would essentially avoid the courses offered through the curriculum in the offline mode.

9.5 The institution shall notify at the beginning of semester the list of the online learning courses eligible for credit transfer in the forthcoming Semester.

9.6 The institution shall also ensure that the student has to complete the course and produce the course completion certificate as per the academic schedule given for the regular courses in that semester

9.7 The institution shall designate a faculty member as a Mentor for each course to guide the students from registration till completion of the credit course.

9.8 The college shall ensure no overlap of SWAYAM MOOC exams with that of the examination schedule. In case of delay in SWAYAM results, the college will re-issue the marks sheet for such students.

9.9 Student pursuing courses under MOOCs shall acquire the required credits only after successful completion of the course and submitting a certificate issued by the competent authority along with the percentage of marks and grades.

9.10 The institution shall submit the following to the examination section of the college:

a) List of students who have passed MOOC courses in the current semester along with the certificates of completion.

b) Undertaking form filled by the students for credit transfer.

9.11 The college shall resolve any issues that may arise in the implementation of this policy from time to time and shall review its credit transfer policy in the light of periodic changes brought by UGC, SWAYAM, NPTEL and state govt. **Note:** Students shall also be permitted to register for MOOCs offered through online platforms other than SWAYAM NPTEL. In such cases, credit transfer shall be permitted only after seeking approval of the college at least three months prior to the commencement of the semester.

10. **Re-registration for Improvement of Internal Evaluation Marks**:

A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination

10.1 The candidate should have completed the course work and obtained examinations results for **I, II and III** semesters.

10.2 The candidate should have passed all the subjects for which the Internal Evaluation marks secured are more than 50%.

10.3 Out of the subjects the candidate has failed in the examination due to Internal Evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of **three** Theory subjects for Improvement of Internal evaluation marks.

10.4 The candidate has to re-register for the chosen subjects and fulfill the academic requirements.

10.5 For reregistration the candidates have to apply to the college by paying the requisite fees and get approval from the college before the start of the semester in which re-registration is required

10.6 In the event of availing the Improvement of Internal evaluation marks, the internal evaluation marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

11. Evaluation of Project/Research Work:

The Project work shall be initiated at the beginning of the III Semester and the duration of the Project is of two semesters. Evaluation of Project work is for 300 marks with 200 marks for internal evaluation and 100 marks for external evaluation. Internal evaluation of the Project Work – I & Project work – II in III & IV semesters respectively shall be for 100 marks each. External evaluation of final Project work viva voce in IV semester shall be for 100 marks.

A Project Review Committee (PRC) shall be constituted with the Head of the Department as Chairperson, Project Supervisor and one faculty member of the department offering the M.Pharm. program.

11.1 A candidate is permitted to register for the Project Work in III Semester after satisfying the attendance requirement in all the subjects, both theory and laboratory (in I & II semesters).

11.2 A candidate is permitted to submit Project dissertation with the approval of PRC. The candidate has to pass all the theory, practical and other courses before submission of the Thesis.

11.4 Project work shall be carried out under the supervision of teacher in the parent department concerned.

11.5 A candidate shall be permitted to work on the project in an industry/research organization on the recommendation of the Head of the Department. In such cases,one of the teachers from the department concerned would be the internal guide and an expert from the industry/ research organization concerned shall act as co-supervisor/ external guide. It is mandatory for the candidate to make full disclosure of all data/results on which they wish to base their dissertation. They cannot claim confidentiality simply because it would come into conflict with the Industry's or R&D laboratory's own interests. A certificate from the external supervisor is to be included in the dissertation.

11.6 Continuous assessment of Project Work - I and Project Work – II in III & IV semesters respectively will be monitored by the PRC.

11.7 The candidate shall submit status report by giving seminars in three different phases (two in III semester and one in IV semester) during the project work period. These seminar reports must be approved by the PRC before submission of the Project Thesis.

11.8 After registration, a candidate must present in Project Work Review - I, in consultation with his Project Supervisor, the title, objective and plan of action of his Project work to the PRC for approval within four weeks from the commencement of III Semester. Only after obtaining the approval of the PRC can the student initiate the project work.

11.9 The Project Work Review - II in III semester carries internal marks of 100.

Evaluation should be done by the PRC for 50 marks and the Supervisor will evaluate the work for the other 50 marks. The Supervisor and PRC will examine the Problem Definition, Objectives, Scope of Work, Literature Survey in the same domain and progress of the Project Work.

11.10 A candidate has to secure a minimum of 50% of marks to be declared successful in Project Work Review - II. Only after successful completion of Project Work Review – II, candidate shall be permitted for Project Work Review – III in IV Semester. The unsuccessful students in Project Work Review - II shall reappear for it as and when supplementary examinations are conducted.

11.11 The Project Work Review - III in IV semester carries 100 internal marks.

Evaluation should be done by the PRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The PRC will examine the overall progress of the Project Work and decide whether or not eligible for final submission. A candidate has to secure a minimum of 50% of marks to be declared successful in Project Work Review - III. If he fails to obtain the required minimum marks, he has to reappear for Project Work Review - III after a month.

11.12 . For the approval of PRC the candidate shall submit the draft copy of dissertation to the Head of the Department and make an oral presentation before the PRC.

11.13. After approval from the PRC, the students are required to submit a report showing that the plagiarism is within 30%. The dissertation report will be accepted only when the plagiarism is within 30%, which shall be submitted along with the dissertation report.

11.14. Research paper related to the Project Work shall be published in conference proceedings/UGC recognized journal. A copy of the published research paper shall be attached to the dissertation.

11.15 . After successful plagiarism check and publication of research paper, three copies of the dissertation certified by the supervisor and HOD shall be submitted to the College.

11.16 . The dissertation shall be adjudicated by an external examiner selected by the college. For this, the Principal of the College shall submit a panel of three examiners as submitted by the supervisor concerned and department head for each student. However, the dissertation will be adjudicated by one examiner nominated by the college.

11.17 . If the report of the examiner is not satisfactory, the candidate shall revise and resubmit the dissertation, in the time frame as decided by the PRC. If report of the examiner is unfavorable again, the thesis shall be summarily rejected. The candidate has to reregister for the project and complete the project within the stipulated time after taking the approval from the college.

11.18. If the report of the examiner is satisfactory, the Head of the Department shall coordinate and make arrangements for the conduct of Project Viva voce exam.

11.19. The Project Viva voce examinations shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who has adjudicated the dissertation. For Dissertation Evaluation (Viva voce) in IV Sem. there are external marks of 100 and it is evaluated by external examiner. The candidate has to secure a minimum of 50% marks in Viva voce exam.

11.20. If he fails to fulfill the requirements as specified, he will reappear for the Project Viva voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree.

12. Credits for Co-curricular Activities

The credits assigned for co-curricular activities shall be given by the principals of the colleges and the same shall be submitted to the examination branch.

A Student shall earn 02 credits under the head of co-curricular activities, viz., attending Conference, Scientific Presentations and Other Scholarly Activities.

Following are the guidelines for awarding Credits for Co-curricular Activities

Name of the Activity	Maximum Credits / Activity
Participation in National Level Seminar/ Conference / Workshop /Training programs (related to the specialization of the student)	1
Participation in International Level Seminar / Conference / workshop/Training programs held outside India (related to the specialization of the student)	2
Academic Award/Research Award from State Level/National Agencies	1
Academic Award/Research Award from International Agencies	2
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	1
Research / Review Publication in International Journals with Editorial board outside India (Indexed in Scopus / Web of Science)	2

Note:

i) Credit shall be awarded only for the first author. Certificate of attendance and participation in a Conference/Seminar is to be submitted for awarding credit.

ii) Certificate of attendance and participation in workshops and training programs (Internal or External) is to be submitted for awarding credit. The total duration should be at least one week.

13. Grading:

As a measure of the student's performance, a 10-point Absolute Grading System using the following Letter Grades and corresponding percentage of marks shall be followed:

After each course is evaluated for 100 marks, the marks obtained in each course will be converted to a corresponding letter grade as given below, depending on the range in which the marks obtained by the student fall.

Structure of Grading of Academic Performance

Range in which the marks in the subject fall	Grade	Grade points Assigned
≥ 90	S (Superior)	10
≥ 80 < 90	A (Excellent)	9
≥ 70 < 80	B (Very Good)	8
≥ 60 < 70	C (Good)	7
≥ 50 < 60	D (Pass)	6
< 50	F (Fail)	0
Absent	Ab (Absent)	0

i) A student obtaining Grade 'F' or Grade 'Ab' in a subject shall be considered failed and will be required to reappear for that subject when it is offered the next supplementary examination.

ii) For noncredit audit courses, "Satisfactory" or "Unsatisfactory" shall be indicated instead of the letter grade and this will not be counted for the computation of SGPA/CGPA/Percentage.

Computation of Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA):

The Semester Grade Point Average (SGPA) is the ratio of sum of the product of the number of credits with the grade points scored by a student in all the courses taken by a student and the sum of the number of credits of all the courses undergone by a student, i.e.,

$SGPA = \Sigma (C_i \times G_i)/\Sigma C_i$

where, C_i is the number of credits of the i^{th} subject and G_i is the grade point scored by the student in the i^{th} course.

i) The Cumulative Grade Point Average (CGPA) will be computed in the same manner considering all the courses undergone by a student over all the semesters of a program, i.e.,

$CGPA = \Sigma (C_i \times S_i)/ \Sigma C_i$

where "S_i" is the SGPA of the i^{th} semester and C_i is the total number of credits up to that semester.

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

iii) While computing the SGPA the subjects in which the student is awarded Zero grade points will also be included.

Grade Point: It is a numerical weight allotted to each letter grade on a 10-point scale. Letter Grade: It is an index of the performance of students in a said course. Grades are denoted by letters S, A, B, C, D and F.

14. Award of Class:

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Pharm. Degree, he shall be placed in one of the following three classes:

Class Awarded	**Percentage of Marks to be secured**
First Class with Distinction	≥70%
First Class	< 70% ≥ 60%
Pass Class	< 60% ≥ 50%

15. **Exit Policy:** The student shall be permitted to exit with a PG Diploma based on his/her request to the college through the respective institution at the end of first year subject to passing all the courses in first year.

The college BoS/Academicv Council shall resolve any issues that may arise in the implementation of this policy from time to time and shall review the policy in the light of periodic changes brought by UGC, PCI, AICTE and State government.

16. Withholding of Results:

If the candidate has any case of in-discipline pending against him, the result of the candidate shall be withheld, and he will not be allowed/promoted into the next higher semester. The issue of degree is liable to be withheld in such cases.

17. **Transitory Regulations**

Discontinued, detained, or failed candidates are eligible for readmission as and when the semester is offered after fulfilment of academic regulations. Candidates who have been detained for want of attendance or not fulfilled academic requirements or who have failed after having undergone the course in earlier regulations or have discontinued and wish to continue the course are eligible for admission into the unfinished semester from the date of commencement of class work with the same or equivalent subjects as and when subjects are offered, subject to Section 2 and they will follow the academic regulations into which they are readmitted.

18. General:

18.1 The academic regulations should be read as a whole for purpose of any interpretation.

18.2 Disciplinary action for Malpractice/improper conduct in examinations is appended.

18.3 There shall be no places transfer within the constituent colleges and affiliated colleges of Jawaharlal Nehru Technological University, Anantapur.

18.4 Where the words “he”, “him”, “his”, occur in the regulations, they include “she”, “her”, “hers”.

18.5 In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Head of the institute is final.

18.6 The college may change or amend the academic regulations or syllabi at any time and the changes or amendments shall be made applicable to all the students on rolls with effect from the dates notified by the University.

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RULES FOR

DISCIPLINARY ACTION FOR MALPRACTICES / IMPROPER CONDUCT IN EXAMINATIONS

	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 subject 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 subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject 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 subject 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 subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. 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 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 subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for four consecutive semesters from class work and all examinations if his involvement is established. Otherwise, the candidate is debarred for two consecutive semesters from class work and all 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 subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all 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 subject only.
6.	Refuses to obey the orders of the Chief Superintendent /Assistant - Superintendent /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 officer-in charge 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 officer-in-charge, 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.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. If the candidate physically assaults the invigilator/ officer-in-charge 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.
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 subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all 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 subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining

		examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person (s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject only or in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester / year examinations, depending
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the exam branch for further action to award suitable punishment.	

1. Malpractices identified by squad or special invigilators
2. Punishments to the candidates as per the above guidelines.
3. Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
4. A show cause notice shall be issued to the college.
5. Impose a suitable fine on the college.
6. Shifting the examination center from the college to another college for a specific period of not less than one year.

Note:

Whenever the performance of a student is cancelled in any subject/subjects due to Malpractice, he has to register for End Examinations in that subject/subjects consequently and has to fulfil all the norms required for the award of Degree.

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M.PHARM. PHARMACEUTICAL ANALYSIS (MPA)

COURSE STRUCTURE & SYLLABI

SEMESTER – I

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	24MPA101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	24MPA102T	Advanced Pharmaceutical Analysis	4	-	-	4
3.	24MPA103T	Pharmaceutical and Food Analysis	4	-	-	4
4.	24MPA104T	Quality Control And Quality Assurance	4	-	-	4
5.	24MPA105P	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	24MPA106P	Pharmaceutical and Food Analysis Lab	-	-	6	3
7.	24MAC101a 24MAC101b 24MAC101c	**Audit Course – I (Any one)** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	24MPA107P	Seminar/Assignment/Mini Project-I	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	24MPA201T	Advanced Instrumental Analysis	4	-	-	4
2.	24MPA202T	Modern Bio-Analytical Techniques	4	-	-	4
3.	24MPA203T	Pharmaceutical Validation	4	-	-	4
4.	24MPA204T	Herbal and Cosmetic Analysis	4	-	-	4
5.	24MPA205P	Advanced Instrumental Analysis Lab	-	-	6	3
6.	24MPA206P	Modern Bio-Analytical Techniques Lab	-	-	6	3
7.	24MAC201a 24MAC201b 24MAC201c	**Audit Course – II (Any One)** Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	24MPA207P	Seminar/Assignment/Mini Project-II	-	1	6	4
		Total	18	1	18	26

SEMSTER – III

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	24MPA301T	Research Methodology and Intellectual Property Right	4	-	-	4
2.	24MEC301d 24MEC301f 24MEC301e	**Open Electives (Any one)** Biological Screening methods Stability of Drugs and Dosage forms Pharmacoepidemiology and Pharmacoeconomics	3	-	-	3
3.	24MPA302P	Teaching Practice/Assignment	-	-	4	2
4.	24MPA303P	Comprehensive viva voce	-	-	4	2
5.	24MPA304P	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER – IV

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	24MPA401P	Co-Curricular Activities	2			2
2.	24MPA402P	Research Work – II	3		30	8
3.	24MPA4PVV	Project Work Viva Voce	-	-	-	10
		Total	5		30	20

Schemes for internal assessments and end semester examinations semester wise

Course Code	Course	Internal Assessment				End Semester Examinations		Total marks
		Continuous mode/Online Examination	Sessional Examinations		Total	Marks	Duration	
		Marks	Marks	Duration				
Semester-I								
24MPA101T	Modern Pharmaceutical Analytical Techniques	10	30	2 Hrs	40	60	3 Hrs	100
24MPA102T	Advanced Pharmaceutical Analysis	10	30	2 Hrs	40	60	3 Hrs	100
24MPA103T	Pharmaceutical and Food Analysis	10	30	2 Hrs	40	60	3 Hrs	100
24MPA104T	Quality Control And Quality Assurance	10	30	2 Hrs	40	60	3 Hrs	100
24MPA105P	Modern Pharmaceutical Analytical Techniques Lab	20	20	3 Hrs	40	60	3 Hrs	100
24MPA106P	Pharmaceutical and Food Analysis Lab	20	20	3 Hrs	40	60	3 Hrs	100
24MAC101a	English for Research paper writing	-	40	2 Hrs	40	-	-	40
24MAC101b	Disaster Management							
24MAC101c	Sanskrit for Technical Knowledge							
24MPA107P	Seminar/Assignment /Mini Project-I	-	-	-	-	-	-	100
Total Marks		**80**	**200**	-	**280**	**360**	-	**740**

Course Code	Course	Internal Assessment				End Semester Examinations		Total marks
		Continuous mode/Online Examination	Sessional Examinations		Total	Marks	Duration	
		Marks	Marks	Duration				
Semester-II								
24MPA201T	Advanced Instrumental Analysis	10	30	2 Hrs	40	60	3 Hrs	100
24MPA202T	Modern Bio-Analytical Techniques	10	30	2 Hrs	40	60	3 Hrs	100
24MPA203T	Pharmaceutical Validation	10	30	2 Hrs	40	60	3 Hrs	100
24MPA204T	Herbal and Cosmetic Analysis	10	30	2 Hrs	40	60	3 Hrs	100
24MPA205P	Advanced Instrumental Analysis Lab	20	20	3 Hrs	40	60	3 Hrs	100
24MPA206P	Modern Bio-Analytical Techniques Lab	20	20	3 Hrs	40	60	3 Hrs	100
24MAC201a	Pedagogy Studies	-	40	2 Hrs	40	-	-	40
24MAC201b	Stress Management for Yoga							
24MAC201b	Personality Development through Life Enlightenment Skills							
24MPA207P	Seminar/Assignment/ Mini Project-I	-	-	-	-	-	-	100
Total Marks		**80**	**200**	**-**	**280**	**360**	**-**	**740**

Course Code	Course	Internal Assessment				End Semester Examinations		Total marks
		Continuous mode/Online Examination	Sessional Examinations		Total	Marks	Duration	
		Marks	Marks	Duration				
Semester-III								
24MPA301T	Research Methodology and Intellectual Property Rights	10	30	2 Hrs	40	60	3 Hrs	100
24MEC301d	Biological Screening methods	10	30	2 Hrs	40	60	3 Hrs	100
24MEC301f	Stability of Drugs and Dosage forms							
24MEC301e	Pharmacoepidemiology and Pharmacoeconomics							
24MPA302P	Teaching Practice/Assignment	-	-	-	-	-	-	100
24MPA303P	Comprehensive viva voce	-	-	-	-	-	-	100
24MPA304P	Research Work - I	-	-	-	-	-	-	100
Total Marks		**20**	**60**	**-**	**80**	**120**	**-**	**500**

Course Code	Course	Internal Assessment				End Semester Examinations		Total marks
		Continuous mode/Online Examination	Sessional Examinations		Total	Marks	Duration	
		Marks	Marks	Duration				
Semester-IV								
24MPA401P	Co-Curricular Activities	-	-	-	-	-	-	100
24MPA402P	Research Work – II	-	-	-	-	-	-	100
24MPA4PVV	Project Work Viva Voce	-	-	-	-	-	-	100
Total Marks		**0**	**0**	**-**	**0**	**0**	**-**	**300**

SEMESTER-I

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C	MARKS
24MPA101T		4	0	0	4	100

Course Category	Core Course

Course Objective

The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcomes

CO1	To understand the basic principles of various spectroscopic techniques, instrumentation and applications in pharmaceutical analysis.
CO2	To understand the principles, instrumentation and applications of NMR spectroscopy the structure determination of compounds.
CO3	Able to apply the mass spectrometry for the analysis if mass and structure of pharmaceutical compounds
CO4	Able to separate various sample mixtures by the application of various chromatographic techniques
CO5	To understand the concept of electrophoresis, crystallography and immune-assays in the field of pharmaceutical analysis

UNIT I — **10 Hrs**

UV-Visible spectroscopy

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

UNIT II — **10 Hrs**

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, Data Interpretation.

UNIT III — **10 Hrs**

NMR spectroscopy

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy

UNIT IV — **10 Hrs**

Mass Spectroscopy

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

UNIT V — **10 Hrs**

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography;	b) High Performance Thin Layer Chromatography
c) Paper Chromatography;	d) Column chromatography
e) Gas chromatography;	f) High Performance Liquid chromatography
g) Affinity chromatography;	h) Gel Chromatography

i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Reference textbooks/Additional reading

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.
4. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
5. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,T imothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
8. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
9. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
10. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
11. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi. Organic Chemistry by I. L. Finar
12. Quantitative Analysis of Drugs by D. C. Garrett
13. HPTLC by P.D. Seth
14. Indian Pharmacopoeia 2007
15. High Performance thin layer chromatography for the analysis of medicinal plants by Eike,Reich, Anne Schibli
16. Introduction to instrumental analysis by Robert. D. Braun

Course Code	ADVANCED PHARMACEUTICAL ANALYSIS	L	T	P	C	MARKS
24MPA102T		4	0	0	4	100

Course Category	Core Course

Course Objective

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phyto-pharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Course Outcomes

CO1	Able to identify, estimate and report the specifications of various impurities in pharmaceutical compounds
CO2	To develop a stability testing protocol for various drug substances and pharmaceutical formulations
CO3	To develop analytical methods for the characterization of impurities in drug substances and products
CO4	To understand the concept of stability testing of phytopharmaceuticals and bioassays of various vaccines.
CO5	To understand the principles of various immunoassays and their applications in pharmacy.

UNIT I — **10 Hrs**

Impurity and stability studies

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines 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

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT II — **10 Hrs**

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

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.

UNIT III — **10 Hrs**

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. Photo stability testing guidelines, ICH stability guidelines for biological products

UNIT IV — **10 Hrs**

Stability testing of phytopharmaceuticals

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

Biological tests and assays of the following
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. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

UNIT V		**10 Hrs**

Immunoassays (IA)

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.

Reference textbooks/Additional reading

1. Vogel's text book of chemical analysis, Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS
3. publishers, New Delhi, 1997.
4. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley& Sons, 1982.102.
5. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
8. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
9. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.
10. Methods of sampling and microbiological examination of water, first revision, BIS
11. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
12. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005
13. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
14. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
15. ICH Guidelines for impurity profiles and stability studies.

Course Code	PHARMACEUTICAL AND FOOD ANALYSIS	L	T	P	C	MARKS
24MPA103T		4	0	0	4	100

Course Category	Core Course

Course Objective

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products

Course Outcomes

CO1	Able to understand the properties, classify and analyze carbohydrates in food and related samples.
CO2	Able to understand the properties, classify and analyze lipids and vitamins in food and related samples.
CO3	Able to understand the properties, classify and analyze food additives, pigments and dyes in food and related samples.
CO4	To perform the analysis of various milk and beverages and their related products
CO5	To identify the pesticides in various food and related products.

UNIT I — **10 Hrs**

Carbohydrates

Classification and properties of food carbohydrates, General methods of analysis 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

UNIT II — **10 Hrs**

Lipids

Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

Vitamins

Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT III — **10 Hrs**

Probiotics

Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT IV — **10 Hrs**

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 dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT V — **10 Hrs**

Milk (constituents and milk products)

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.

Pesticides Analysis in food like organophosphorus and organochlorine

Knowledge in food regulations and legislations.

Reference textbooks/Additional reading
1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976 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, 1997. 4. Analysis of Food constituents – Multon, Wiley VCH. 5. Dr. William Horwitz, Official methods of analysis of AOAC International 6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman 7. Indian Pharmacopoeia 2012 8. Remington's Pharmaceutical Sciences by Alfonso and Gennaro

Course Code	QUALITY CONTROL AND QUALITY ASSURANCE	L	T	P	C	MARKS
24MPA104T		4	0	0	4	100

Course Category	Core Course

Course Objective

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcomes

CO1	Able to demonstrate the concept of QC, QA & GLP in pharma laboratories
CO2	Understand and implement the cGMP practices in various regulatory setups
CO3	Perform the analysis and QC of various drugs and formulations and pharmaceutical containers
CO4	Practice good documentation of all procedures, records and reports in pharmaceutical industry
CO5	Understand the manufacturing and operation control in pharmaceutical industry

UNIT I — **10 Hrs**

Quality Control and Quality Assurance

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.

UNIT II — **10 Hrs**

cGMP

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 guidelines.

UNIT III — **10 Hrs**

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.

UNIT IV — **10 Hrs**

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.

UNIT V — **10 Hrs**

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.

Reference textbooks/Additional reading

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, 2nd 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, 3rd 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, 4thedition, 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.

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C	MARKS
24MPA105P		0	0	6	3	100

Course Category	Core Course

Course Objective

The main objective of this course is to impart the learner the knowledge to handle the sophisticated analytical instruments and perform the analytical methods using these instruments for the analysis of drug and other analytical samples.

Course Outcomes

CO1	To perform the analysis of pharmacopoeial compounds by various spectroscopic techniques
CO2	To determine the functional groups in various organic compounds
CO3	To separate and estimate various sample mixtures by various chromatographic techniques
CO4	To calibrate various analytical instruments like UV – Visible Spectrophotometer/ HPLC/ GC/ FTIR
CO5	To learn the cleaning validation of equipment.

List of Experiments

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Qunatitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Preparation of Master Formula Record.
14. Preparation of Batch Manufacturing Record.

Course Code	PHARMACEUTICAL AND FOOD ANALYSIS LAB	L	T	P	C	MARKS
24MPA106P		0	0	6	3	100

Course Category	Core Course

Course Objective

The main objective of this course is to impart the knowledge to the learner to understand and perform he analysis of various food products and excipients in various sample matrices.

Course Outcomes

CO1	Able to identify and estimate main constituents of various food products
CO2	To detect the presence of pesticides in food and related products
CO3	To analyze the various dairy products

List of Experiments

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
11. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
12. Assay of any two Antihistamines (API & dosage forms) official in IP
13. Assay of any two Diuretics (API & dosage forms) official in IP

AUDIT COURSE-I

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C	MARKS
24MAC101a		2	0	0	0	40

Course Category	Audit Course

Course Objective

Understand the essentials of writing skills and their level of readability. Learn about what to write in each section. Ensure qualitative presentation with linguistic accuracy

Course Outcomes

CO1	Understand that how to improve your writing skills and level of readability
CO2	Learn about what to write in each section
CO3	Understand the skills needed when writing a Title
CO4	Ensure the good quality of paper at very first-time submission

UNIT I	10 Hrs
Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity	
UNIT II	**10 Hrs**
Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization	
UNIT III	**10 Hrs**
Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.	
UNIT IV	**10 Hrs**
Key skills needed for writing a Title, Abstract, and Introduction	
UNIT V	**10 Hrs**
Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions	

Reference textbooks/Additional reading

1. Goldbort, Model Curriculum of Engineering & Technology PG Courses [Volume-I]
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

Course Code	DISASTER MANAGEMENT	L	T	P	C	MARKS
24MAC101b		2	0	0	0	40

Course Category	Audit Course

Course Objective

Learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.

Course Outcomes

CO1	Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
CO2	Develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
CO3	Critically understand the strengths and weaknesses of disaster management approaches, planning and programming in different countries, particularly their home country or the countries they work in

UNIT I — **10 Hrs**

Introduction:

Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post- Disaster Diseases and Epidemics

UNIT II — **10 Hrs**

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT III — **10 Hrs**

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT IV — **10 Hrs**

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT V — **10 Hrs**

Disaster Mitigation: Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Reference textbooks/Additional reading

1. R.Nishith,SinghAK,"Disaster Management in India:Perspectives, issues and strategies "'New Royal book Company.

2.	Sahni, Pardeep Et.Al.(Eds.),"Disaster Mitigation Experiences And Reflections",Prentice Hall Of India, New Delhi.
3.	GoelS.L.,Disaster Administration And Management-Text And Case Studies",Deep&Deep Publication Pvt. Ltd., New Delhi

Course Code	SANSKRIT FOR TECHNICAL KNOWLEDGE	L	T	P	C	MARKS
24MAC101c		2	0	0	0	40

Course Category	Audit Course

Course Objective

To get a Learning of Sanskrit to improve brain functioning. Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power. The engineering scholars equipped with Sanskrit will be able to explore the huge Knowledge from ancient literature.

Course Outcomes

CO1	Understanding basic Sanskrit language
CO2	Ancient Sanskrit literature about science & technology can be understood
CO3	Being a logical language will help to develop logic in students

UNIT I		**10 Hrs**
Alphabets in Sanskrit		
UNIT II		**10 Hrs**
Past/Present/Future Tense, Simple Sentences		
UNIT III		**10 Hrs**
Order, Introduction of roots		
UNIT IV		**10 Hrs**
Technical information about Sanskrit Literature		
UNIT V		**10 Hrs**
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics		

Reference textbooks/Additional reading

1. "Abhyaspustakam" –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit " Prat hama Deeksha- Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. "India's Glorious ScientificTradition" Suresh Soni, Ocean books (P) Ltd.,New Delhi

SEMESTER-II

Course Code	ADVANCED INSTRUMENTAL ANALYSIS	L	T	P	C	MARKS
24MPA201T		4	0	0	4	100

Course Category	Core Course

Course Objective

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Course Outcomes

CO1	To understand the advancements in HPLC techniques and their applications in pharmaceutical analysis
CO2	Apply various chromatographic samples for the separattion and estimation of pharmaceutical and biological compounds
CO3	Able to apply SFC and CE techniques for the separation and analysis of complex mixtures
CO4	To understand the importance of various tandem mass spectrometric methods for advanced analysis of samples
CO5	Use the concepts of H1-NMR, C13-NMR and 2d-NMR techniques for deducing the structure of various organic compounds

UNIT I — **10 Hrs**

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, reversed phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT II — **10 Hrs**

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.

UNIT III — **10 Hrs**

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.

UNIT IV — **10 Hrs**

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.		
UNIT V		**10 Hrs**
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-Dand 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.		

Reference textbooks/Additional reading

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. Organic Spectroscopy - William Kemp, 3rd 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, 3rd 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.

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES	L	T	P	C	MARKS
24MPA202T		4	0	0	4	100

Course Category	Core Course

Course Objective

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Course Outcomes

CO1	Able to prepare the sample for analysis using various sample extraction techniques
CO2	Able to explain the basic concepts of biopharmaceutical considerations in in-vitro and in-vivo studies
CO3	To understand the concept of pharmacokinetics and toxicokinetics
CO4	To learn various cell culture techniques and their analysis
CO5	To able design and develop methods for metabolite identification in biological matrices.

UNIT I — **10 Hrs**

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

UNIT II — **10 Hrs**

Biopharmaceutical Consideration

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.

UNIT III — **10 Hrs**

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

UNIT IV — **10 Hrs**

Cell culture techniques

Cell culture techniques Basic equipment's 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 cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT V — **10 Hrs**

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.

Reference textbooks/Additional reading	
1.	Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.
2.	Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3.	Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd 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, 2ndEdition, John Wiley & Sons, New Jercy. USA.
6.	Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2ndEdition, Marcel Dekker, Newyork, USA. 1997.
7.	Chromatographic methods in clinical chemistry & Toxicology – Roger LBertholf, 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.
11.	Palmer

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C	MARKS
24MPA203T		4	0	0	4	100

Course Category	Core Course

Course Objective

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application

Course Outcomes

CO1	Able to explain the concept of validation and qualification in pharmaceutical industry
CO2	To qualify and calibrate various analytical instruments
CO3	To understand the qualification of various utility systems and cleaning of equipment in pharmaceutical industry
CO4	Able to develop and validate analytical method as per regulatory guidelines
CO5	To understand the concept of IPR, Patents and copyrights in pharmaceutical industry setup

UNIT I — **10 Hrs**

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.

UNIT II — **10 Hrs**

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.

UNIT III — **10 Hrs**

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 (CIP).

UNIT IV — **10 Hrs**

Analytical method validation

General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

UNIT V — **10 Hrs**

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.

Reference textbooks/Additional reading

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
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 byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

Course Code	HERBAL AND COSMETIC ANALYSIS	L	T	P	C	MARKS
24MPA204T		4	0	0	4	100

Course Category	Core Course

Course Objective

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipment used in cosmetic industries for the purpose.

Course Outcomes

CO1	Able to understand various herbal remedies and herbal drug standardization procedures
CO2	Identify adulteration and detoriation of herbal drugs and understand global regulatory requirements in herbal drug industry
CO3	Analyze various types of herbal drugs and products as per official monographs
CO4	Understand Challenges in monitoring the safety of herbal medicines
CO5	Study and evaluation of various types of cosmetic preparation

UNIT I — **10 Hrs**

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

UNIT II — **10 Hrs**

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.

UNIT III — **10 Hrs**

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 Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT IV — **10 Hrs**

Herbal drug-drug interaction

General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

UNIT V — **10 Hrs**

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 Standards

Reference textbooks/Additional reading

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
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.

Course Code	ADVANCED INSTRUMENTAL ANALYSIS LAB	L	T	P	C	MARKS
24MPA205P		0	0	6	3	100

Course Category	Core Course

Course Objective

The main objective of this course is to able to interpret the organic compounds and various drugs by using the combination of spectroscopic techniques and also to understand the operation and calibration of analytical instruments.

Course Outcomes

CO1	Able to interpret the structure of an organic compound by the application of various spectroscopic techniques like UV, IR, NMR & Mass
CO2	Separation and estimation of various biomolecules by HPLC techniques
CO3	Quality control of various raw materials dosage forms

List of Experiments

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. Testing of related and foreign substances in drugs and raw materials
8. Assay of raw materials as per official monographs
9. Calibration of UV – Visible Spectrophtometer/ HPLC/ GC/ FTIR
10. Cleaning validation of any one analytical equipment

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES LAB	L	T	P	C	MARKS
24MPA206P		0	0	6	3	100

Course Category	Core Course

Course Objective

The main objective of this course is to understand the process of bio-analytical method development and validation in various sample matrices.

Course Outcomes

CO1	Able to prepare the protocols for bioanalytical methods
CO2	To perform analysis of drugs and other substances in biological fluids
CO3	To perform quality control methods for herbal materials/ Medicinal plant materials

List of Experiments

1. Protocol preparation and performance of bioanalytical method validation
2. Protocol preparation for the conduct of BA/BE studies according to guidelines
3. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques
4. Isolation of analgesics from biological fluids (blood serum and urine)
5. Identification of anti-histaminics drug in urine by TLC
6. Extraction of drugs and metabolites from biological matrices by SPE/LLE
7. HPLC separation of modern drug from plasma and its formulations (Diclofenac)
8. Stability indicating method development by HPLC of any API
9. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis
10. Quality control methods for herbal materials/ Medicinal plant materials

AUDIT COURSE-II

Course Code	PEDAGOGY STUDIES	L	T	P	C	MARKS
24MAC201a		2	0	0	0	40

Course Category	Audit Course

Course Objective

Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers. Identify critical evidence gaps to guide the development.

Course Outcomes

CO1	What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
CO2	What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
CO3	How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT I		10 Hrs

Introduction and Methodology:
Aims and rationale, Policy background, Conceptual framework and terminology. Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions. Overview of methodology and Searching.

UNIT II		10 Hrs

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT III		10 Hrs

Evidence on the effectiveness of pedagogical practices. Methodology for the in depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT IV		10 Hrs

Professional development: alignment with classroom practices and follow-up support. Peer support. Support from the head teacher and the community. Curriculum and assessment. Barriers to learning: limited resources and large class sizes.

UNIT V		10 Hrs

Research gaps and future directions
Research design. Contexts. Pedagogy. Teacher education. Curriculum and assessment. Dissemination and research impact.

Reference textbooks/Additional reading

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.
4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.

5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, ‘learning to read’ campaign.
7. 7. www.pratham.org/images/resource%20working%20paper%202.pdf.

Course Code	STRESS MANAGEMENT FOR YOGA	L	T	P	C	MARKS
24MAC201b		2	0	0	0	40

Course Category	Audit Course
Course Objective	
To achieve overall health of body and mind. To overcome stress	
Course Outcomes	
CO1	Develop healthy mind in a healthy body thus improving social health
CO2	Improve efficiency

UNIT I		**10 Hrs**
Definitions of Eight parts of yog. (Ashtanga)		
UNIT II		**10 Hrs**
Yam and Niyam.		
UNIT III		**10 Hrs**
Do`s and Don't's in life. i) Ahinsa, satya, astheya, bramhacharya and aparigraha ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan		
UNIT IV		**10 Hrs**
Asan and Pranayam		
UNIT V		**10 Hrs**
i) Various yoga poses and their benefits for mind & body ii)Regularization of breathing techniques and its effects-Types of pranayam		

Reference textbooks/Additional reading

1. Yogic Asanas for Group Training-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

Course Code	PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS	L	T	P	C	MARKS
24MAC201c		2	0	0	0	40

Course Category	Audit Course
Course Objective	
Develop healthy mind in a healthy body thus improving social health also. Improve efficiency	
Course Outcomes	
CO1	To learn to achieve the highest goal happily
CO2	To become a person with stable mind, pleasing personality and determination
CO3	To awaken wisdom in students

UNIT I	**10 Hrs**
Neetisatakam-Holistic development of personality Verses- 19,20,21,22 (wisdom) Verses- 29,31,32 (pride & heroism) Verses- 26,28,63,65 (virtue)	
UNIT II	**10 Hrs**
Neetisatakam-Holistic development of personality Verses- 52,53,59 (dont's) Verses- 71,73,75,78 (do's)	
UNIT III	**10 Hrs**
Approach to day to day work and duties. Shrimad Bhagwad Geeta : Chapter 2-Verses 41, 47,48 Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35 Chapter 18-Verses 45, 46, 48	
UNIT IV	**10 Hrs**
Statements of basic knowledge. Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68 Chapter 12 -Verses 13, 14, 15, 16,17, 18 Personality of Role model.	
UNIT V	**10 Hrs**
Shrimad Bhagwad Geeta: Chapter 2-Verses 17, Chapter 3-Verses 36,37,42, Chapter 4-Verses 18, 38,39 Chapter18 – Verses 37,38,63	

Reference textbooks/Additional reading

1. "SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2. Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

SEMESTER-III

Course Code	RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS	L	T	P	C	MARKS
24MPA301T		4	0	0	4	100

Course Category	Research Course

Course Objective

To understand the research problem
To know the literature studies, plagiarism and ethics
To get the knowledge about technical writing
To analyze the nature of intellectual property rights and new developments
To know the patent rights

Course Outcomes

CO1	To understand the concept of research, different types of research
CO2	Apply biostatistics in the field of research and project work
CO3	Understand the importance of medical research and methods
CO4	Explore the usage of CPSCEA guidelines in animal studies
CO5	Understand basic principles for all medical research-concept of Declaration of Helsinki

UNIT I		10 Hrs

Research Problem

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT II		10 Hrs

Literature review

Effective literature studies approaches, analysis, Plagiarism, Research ethics.

UNIT III		10 Hrs

Report writing

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT IV		10 Hrs

Nature of Intellectual Property

Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT V		10 Hrs

Patent Rights:

Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

Reference textbooks/Additional reading

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
3. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"

4. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
5. Mayall, “Industrial Design”, McGraw Hill, 1992. Niebel, “Product Design”, McGraw Hill, 1974.
6. Asimov, “Introduction to Design”, Prentice Hall, 1962.
7. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New Technological Age”, 2016.
8. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

OPEN ELECTIVES

Course Code	BIOLOGICAL SCREENING METHODS	L	T	P	C	MARKS
24MEC301d		3	0	0	3	100

Course Category	Research Course

Course Objective

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcomes

CO1	How to handle animals
CO2	About various techniques for screening of drugs for different pharmacological activities
CO3	Guidelines and regulations for screening new drug molecules on animals.

UNIT I		10 Hrs

Drug discovery process:

Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery, Regulations. Alternatives to animal screening procedures, cell-line, patch –clamp technique, In-vitro models, molecular biology techniques.

UNIT II		10 Hrs

Bioassays:

Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization.

UNIT III		10 Hrs

Toxicity Evaluations

Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH recommendations).

Preclinical studies: General principles and procedures involved in acute, sub-acute, chronic, teratogenicity, mutagenicity and carcinogenicity.

UNIT IV		10 Hrs

Screening of drugs

Screening of different classes of drugs using micro-organisms. Vitamin and antibiotic assays. Screening methods involved in toxins and pathogens.

UNIT V		10 Hrs

Enzymatic screening methods

α-glucosidase, α- amylase, DNA polymerase, nucleases, L-asparginase, lipases and peptidases.

Reference textbooks/Additional reading

1. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e
2. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc-Graw Hill, USA 2001 10th edition.
3. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
4. Drug Discovery by Vogel's
5. Drug Discovery and evaluation – Pharmacological assays by H.Gerhard.Vogel, 2nd edition, Springer verlag, Berlin, Heidelberg.
6. Tutorial Pharmacy (Vol I and II) by Cooper and Gunns.

Course Code	STABILITY OF DRUGS AND DOSAGE FORMS	L	T	P	C	MARKS
24MEC301f		3	0	0	3	100

Course Category	Research Course

Course Objective

These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes

CO1	Evaluation of stability of solutions, solids and formulations against adverse conditions
CO2	Suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT I		10 Hrs

Drug decomposition mechanisms

1. Hydrolysis and acyl transfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT II		10 Hrs

Solid state chemical decomposition

Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT III		10 Hrs

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT IV		10 Hrs

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT V		10 Hrs

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products. Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.
b) b) Interaction of containers & closure Compatibility Testing.

Reference textbooks/Additional reading

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A.H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.
3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
4. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
5. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
6. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
7. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
8. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
9. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
10. Drug stability: Principles and practices by Jens T. Carstensen
11. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

Course Code	PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS	L	T	P	C	MARKS
24MEC301e		3	0	0	3	100

Course Category	Research Course

Course Objective

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcomes

CO1	Understand the various epidemiological methods and their applications
CO2	Understand the fundamental principles of Pharmacoeconomics
CO3	Identify and determine relevant cost and consequences associated with pharmacy products and services.
CO4	Perform the key Pharmacoeconomics analysis methods
CO5	Understand the Pharmacoeconomic decision analysis methods and its applications.

UNIT I — **10 Hrs**

Introduction to Pharmacoepidemiology

Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses,

prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk:

Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II — **10 Hrs**

Pharmacoepidemiological Methods

Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT III — **10 Hrs**

Introduction to Pharmacoeconomics

Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT IV — **10 Hrs**

Pharmacoeconomic evaluations

Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT V — **10 Hrs**

Health related quality of life (HRQOL)

Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps

involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics

Reference textbooks/Additional reading

1. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
2. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
3. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature
10. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice