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Course Structure and Syllabus

of

M.Pharm
(Pharmaceutical Analysis)

School of Pharmacy and Life Sciences

2024

COURSE STRUCTURE AND SYLLABI

M. Pharm (Pharmaceutical Analysis)

2024-25 Batch

Centurion UNIVERSITY

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School of Pharmacy and Life Sciences
CENTURION UNIVERSITY OF TECHNOLOGY & MANAGEMENT
Odisha-752050, India

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CERTIFICATE

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This is to certify that the syllabus of the M. Pharm (Pharmaceutical Analysis) Programme of the School of Pharmacy and Life sciences is approved in the 14th Academic Council Meeting held on 22nd November 2024.

Dean
School of Pharmacy and Life Sciences
CUTM, Odisha

SCHOOL OF PHARMACY AND LIFE SCIENCES

SCHEME & SYLLABUS

M.PHARM (PHARMACEUTICAL ANALYSIS)

FOR

THE MASTER OF PHARMACY (M. PHARM.)
COURSE REGULATION 2014
(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

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2024

VISION:

To be a globally recognized centre for Teaching, Research and Entrepreneurial Training in Pharmaceutical Sciences and to provide Healthcare services for Societal needs.

MISSION:

- To nurture young minds into knowledgeable, skillful and ethical professionals to serve for the society.
- To support research in diverse ways by launching partnerships and collaborations.
- To ensure affordable health care by developing pharmaceutical formulations using in house resources.
- To inculcate the mindset for entrepreneurship and innovativeness to enrich the healthcare system.

Programme Objectives:

1. To develop advanced knowledge and technical expertise in Pharmacy.
2. To cultivate research skills, innovations and professional practice in the Pharmaceutical industry.
3. To Nurture and support an inclination for higher education and entrepreneurship.

PROGRAMME OUTCOMES (POs):

At successfully completing the M. Pharm program, student should have achieved the following program outcomes mentioned below

Sl No.	Programme Outcomes
PO 1	**Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
PO 2	**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.
PO 3	**Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
PO 4	**Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
PO 5	**Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
PO 6	**Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO 7	**Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
PO 8	**Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
PO 9	**The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
PO 10	**Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
PO11	**Entrepreneurship**: Develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development.

PO 12	**Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

PSO (Program Specific Outcomes)

Sl No.	Program Specific Outcomes
PSO1	**Understanding of Analytical Techniques:** Students will gain an understanding of various analytical techniques used in pharmaceutical analysis, including spectroscopy (UV-Vis, IR, NMR), chromatography (HPLC, GC), titration, and other chemical and physical methods.
PSO2	**Validation and Quality Control:** Students will be able to validate analytical methods, ensuring that they are reliable, accurate, and precise. They will also learn about quality control procedures to monitor the consistency of pharmaceutical products.
PSO3	**Pharmacopeial Standards:** Students will become familiar with various pharmacopeias (e.g., USP, BP, EP) and their role in establishing standards for pharmaceutical analysis.

CHAPTER – I: REGULATIONS

1. Short Title and Commencement
These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission
A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program
The programs of study for M.Pharm. Shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations
Medium of instruction and examination shall be in English.

5. Working days in each semester
Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress
A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure
As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course.

Similarly the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits 23 are distributed semester-wise as shown in Table 5. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 1. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 1.

M.PHARM (PHARMACEUTICAL ANALYSIS)

Table – 1: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
MPA106P	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic analysis	4	4	4	100
MPA205T	Pharmaceutical Analysis Practical II	12	6	12	150
MPA206P	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 2: Course of study for M. Pharm. III Semester

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology Biostatistics*	4	4
MPA302P	Journal Club	1	1
MPA303P	Discussion / Presentation (Proposal Presentation)	2	2
MPA304P	Research Work	28	14
Total		**35**	**21**

* Non-University Exam

Table – 3: Course of study for M. Pharm. IV Semester

(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MPA401P	Journal Club	1	1
MPA402P	Research Work	31	16
MPA403P	Discussion / Final Presentation	3	3
Total		**35**	**20**

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

Table – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. Programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows: A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters. iv. Communicating its recommendation to the Head of the institution on academic matters.
v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 6.

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IVshall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables –6: Schemes for internal assessments and end semester (Pharmaceutical Analysis)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3Hrs	100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPA106P	Seminar/Assignment	-	-	-	-	-	-	-
Total								**650**

Semester II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA204T	Herbal and Cosmetic analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA205T	Pharmaceutical Analysis II	20	30	6 Hrs	50	100	6 Hrs	150
MPA206P	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Tables – 7: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
MPA302P	Journal Club	-	-	-	25	-	-	25
MPA303P	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MPA304P	Research work	-	-	-	-	350	-	350
Total								525

Semester IV								
MPA401P	Journal club	-	-	-	25	-	-	25
MPA402P	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MPA403P	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 8: Scheme for awarding internal assessment: Continuous mode

Theory	
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 9: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95-100	8	10
90-94	6	7.5
85-89	4	5
80-84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

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

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 10. The exact dates of examinations shall be notified from time to time.

Table – 10: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table –11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	0	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student' s grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1 + C2 + C3 + C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example, if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO}{C1 + C2 + C3 + C4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…and S1,S2, S3,….is the SGPA of semester I,II,III,….

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:
First Class with Distinction = CGPA of. 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M. Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condo nation fee.

CHAPTER - II: SYLLABUS

SEMESTER-I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Course Objective:

- To get fundamental knowledge of advanced analytical instrumental techniques for identification, characterization and quantification of drugs
- To handle instruments like NMR, Mass spectrometer, IR, HPLC, GC, etc.
- To perform analysis of elemental impurities

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Analyze*** of various drugs in single and combination dosage forms.	PO1, PO6, PO9, PO12
CO-2	***Analyze*** Chemicals and Excipients	PO1, PO9, PO12
CO-3	***Explain*** general principles and theory of spectroscopy	PO1, PO12
CO-4	***Describe*** various separation techniques by employing chromatographic methods.	PO1, PO12
CO-5	***Understand*** basic principles of biological tests and immunoassay.	PO1, PO3, PO12

THEORY **60 Hours**

10 Hrs

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

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

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

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

10 Hrs

2.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

10 Hrs

3.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

10 Hrs

4.Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

10 Hrs

5.Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

6. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometric.

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating andcooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage anddisadvantages, pharmaceutical applications.

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ADVANCED PHARMACEUTICAL ANALYSIS (MPA102T)

Course Objective:

- To provide an understanding of impurity classification, quantification, and control as per ICH guidelines
- To learn the identification, classification, and control of elemental impurities in pharmaceutical products
- To equip students with the knowledge of stability testing protocols, accelerated stability studies, impurity profiling, and degradant characterization for new drug products and biologicals

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Classify*** and quantify impurities in drug substances and new drug products, in accordance with ICH guidelines, and assess their impact on product quality.	PO1, PO2, PO3, PO12
CO-2	***Report*** and control degradation products in drug products, including the qualification of degradation products and listing them in product specifications.	PO1, PO2, PO3, PO12
CO-3	***Explain*** he principles, classification, and analytical procedures for detecting and reporting residual solvents in drug products, and interpret limits	PO1, PO2, PO3, PO12
CO-4	***D*evelop and implement** stability testing protocols, including batch selection, sampling frequency, and storage conditions	PO1, PO2, PO3, PO12
CO-5	***Perform*** biological tests and assays on vaccines and other biological products, and understand the principles and applications of various immunoassays	PO1, PO2, PO3, PO12

THEORY **60 HOURS**

10 Hrs

1.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

10 Hrs

2.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.

10 Hrs

3.Impurity profiling and degradant 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 degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

10 Hrs

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

10 Hrs

5.Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine

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

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.

REFERENCES

1. Vogel‘s textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.

2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.

3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982. 102

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961. 5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997. 6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series. 7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.

8. Indian Pharmacopoeia Vol I, II & III 2007, 2010, 2014. 9. Methods of sampling and microbiological examination of water, first revision, BIS

10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd

edition, John Wiley & Sons. 11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005

12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.

14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION (MPA103T)

Course Objective:

- To provide students with an in-depth understanding of qualification and validation processes in the pharmaceutical industry
- To enable students to acquire the skills necessary to validate a range of analytical instruments,
- To introduce students to the concept of Intellectual Property (IP), including patents, trademarks, and copyrights

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** and apply the principles of qualification and validation, including the creation of a Validation Master Plan	PO1, PO2, PO3, PO12
CO-2	***Perform*** qualification of key analytical instruments, such as HPLC, GC, and UV-visible spectrophotometers, and laboratory equipment	PO1, PO2, PO3,PO4, PO12
CO-3	**Validate** critical utility systems in pharmaceutical environments, including water systems, HVAC, compressed air, and cleaning systems	PO1, PO2, PO3,PO4, PO12
CO-4	***Validate*** analytical methods according to ICH guidelines and USP standards, ensuring compliance with regulatory requirements for pharmaceutical testing.	PO1, PO2, PO3,PO7, PO12
CO-5	***Demonstrate*** a clear understanding of intellectual property laws and practices relevant to the pharmaceutical industry	PO1, PO2, PO3,PO7, PO12

THEORY **60 HOURS**

1.Introduction: 12 Hrs

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 equipment's.

2. Qualification of analytical instruments: 12 Hrs

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

3.Validation of Utility systems: 12Hrs

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).

4.Analytical method validation: 12Hrs

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

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

5.General Principles of Intellectual Property: 12Hrs

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 application; 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.

REFERECES

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.

FOOD ANALYSIS (MPA104T)

Course Objective:

- To Understand the Chemical Composition and Metabolism of Key Food Components
- To Equip Students with Analytical Techniques for Food Quality and Safety
- To Provide Knowledge on Food Additives, Adulteration, and Regulatory Standards

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***classify,*** analyse, and explain the physiological roles of carbohydrates and proteins in food.	PO1, PO2, PO3, PO12
CO-2	***Analyze*** pesticide residues in food products, including grains, fruits, vegetables, milk, and milk products.	PO1, PO2, PO3, PO12
CO-3	***Acquire the knowledge to classify lipids and analyze fats and oils using standard methods***	PO1, PO2, PO3, PO12
CO-4	***Conduct*** methods for their analysis, and apply microbial assays for B vitamins, helping them understand the significance of vitamins in food and their metabolic roles.	PO1, PO2, PO3, PO9,PO12
CO-5	***Analyse*** common food additives, including preservatives, antioxidants, and flavours.	PO1, PO2, PO3, PO12

THEORY **60 Hours**

1.Carbohydrates: 12 Hrs

classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2.Lipids: 12 Hrs

Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3.Food additives: 12 Hrs

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.

4. General Analytical methods for milk, milk constituents and milk products 12 Hrs

like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

5.Pesticide analysis: 12 Hrs

Effects of pest and insects on various food, use of pesticides in agriculture,pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

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, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL- I (MPA105P)

Course Objective:

- To develop Proficiency in Analytical Techniques for Pharmaceutical and Food Analysis
- To enhance knowledge of Quantitative and Qualitative Analytical Methods
- To Train Students in Calibration and Validation Procedures for Laboratory Instruments

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Analyze*** pharmacopoeial compounds and their formulations using UV-Vis spectrophotometry	PO1, PO2, PO3,PO4, PO12
CO-2	***Have hands-on experience in performing experiments using HPLC and Gas Chromatography***	PO1, PO2, PO3,PO4, PO12
CO-3	***Estimate*** compounds such as riboflavin/quinine sulfate by fluorimetry, determine sodium/potassium levels by flame photometry	PO1, PO2, PO3,PO4, PO12
CO-4	**Skil**l in calibrating essential laboratory instruments, including UV-Visible spectrophotometers, FTIR spectrophotometers, HPLC, GC, and pH meters	PO1, PO2, PO3,PO4, PO12
CO-5	***Gain*** practical experience in analyzing food products for important parameters such as total reducing sugars, fat content, preservatives, pesticide residues, and vitamins.	PO1, PO2, PO3,PO4, PO12

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glassware's
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer

16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

SEMESTER-II

ADVANCED INSTRUMENTAL ANALYSIS (MPA201T)

Course Objective:

- To provide In-Depth Knowledge of Chromatographic Techniques
- To develop Practical Skills in Advanced Instrumentation and Method Development
- To explore the Latest Advances in Chromatography and Mass Spectrometry

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** the principle of High-Performance Liquid Chromatography (HPLC) and its components, including pumps, injectors, detectors, and columns.	PO1, PO2, PO3,PO4, PO12
CO-2	***Gain*** skill in the use of biochromatography techniques such as size exclusion chromatography, ion exchange chromatography, and affinity chromatography	PO1, PO2, PO3,PO4, PO12
CO-3	***Apply*** new developments in chiral separations, including the use of immobilized polysaccharide CSPs (Chiral Stationary Phases), HILIC (Hydrophilic Interaction Liquid Chromatography).	PO1, PO2, PO3,PO4, PO12
CO-4	***Understand*** of mass spectrometry principles, including ionization techniques), mass analyzers and fragmentation patterns.	PO1, PO2, PO3,PO4, PO12
CO-5	***Interpret*** NMR spectra, understanding chemical shifts, spin-spin coupling, and the relaxation processes involved	PO1, PO2, PO3,PO4, PO12

THEORY **60 Hours**

1. 12 Hr

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

2. 12Hrs

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.

3. 12 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.

4. 12 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.

5. 12 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-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

REFERENCES

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

MODERN BIO-ANALYTICAL TECHNIQUES (MPA202T)

Course Objective:

- To develop Proficiency in Analytical Techniques for Pharmaceutical and Food Analysis
- To Enhance Knowledge of Quantitative and Qualitative Analytical Methods.
- To Train Students in Calibration and Validation Procedures for Laboratory Instruments,

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Analyze*** pharmacopoeial compounds and their formulations using UV-Vis spectrophotometry	PO1, PO2, PO3,PO4, PO12
CO-2	***Perform*** experiments using HPLC and Gas Chromatography, with the ability to separate, identify, and quantify compounds in complex mixtures.	PO1, PO2, PO3,PO4, PO12
CO-3	***Estimate*** compounds such as riboflavin/quinine sulfate by fluorimetry, determine sodium/potassium levels by flame photometry, and perform colorimetric drug determinations using various reagents.	PO1, PO2, PO3,PO4, PO12
CO-4	***Gain*** skill in calibrating essential laboratory instruments, including UV-Visible spectrophotometers, FTIR spectrophotometers, HPLC, GC, and pH meters	PO1, PO2, PO3,PO4, PO12
CO-5	***Analyse*** food products for important parameters such as total reducing sugars, fat content, preservatives, pesticide residues, and vitamins	PO1, PO2, PO3,PO4, PO12

THEORY **60 Hours**

1. 12Hrs

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.

2. 12 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.

3. 12 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.

4. 12 Hrs

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

5. 12 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.

REFERENCES

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, 2nd Edition, John Wiley & Sons, New Jercy. USA.

6.Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.

7.Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.

8.Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.

9.Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

10.ICH, USFDA & CDSCO Guidelines.

11.Palmer

QUALITY CONTROL AND QUALITY ASSURANCE (MPA203T)

Course Objective:

- To provide Comprehensive Knowledge of Quality Control and Assurance Systems
- To develop Practical Knowledge of Regulatory Guidelines and Good Manufacturing Practices
- To enhance Understanding of Pharmaceutical Quality Control Procedures and Documentation

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** the evolution, scope, and implementation of Quality Control and Quality Assurance systems in pharmaceutical manufacturing, including GLP, GMP, and ICH guidelines.	PO1, PO2, PO3,PO7, PO12
CO-2	***Apply*** cGMP guidelines (Schedule M, USFDA, WHO, EMEA) in pharmaceutical manufacturing and ensure compliance with international standards.	PO1, PO2, PO3,PO7, PO12
CO-3	***Proficient*** in analyzing raw materials, in-process materials, finished products, and packaging materials, as well as developing specifications in accordance with ICH Q6 and Q3 guidelines.	PO1, PO2, PO3,PO7, PO12
CO-4	***Manage*** pharmaceutical documentation systems, including creating SOPs, maintaining Master Formula and Batch Records, and preparing quality audit reports, ensuring proper retention and retrieval practices.	PO1, PO2, PO3,PO7, PO12
CO-5	***Gain*** practical knowledge of manufacturing operations, including quality control in production, packaging, sanitation, and aseptic processes, as well as managing deviations, change control, and expiry date calculation	PO1, PO2, PO3,PO7, PO12

THEORY **60 Hours**

1. 12 Hrs

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.

2. 12 Hrs

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.

3. 12 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.

4. 12 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.

5. 12 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.

REFERENCES

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, MarcelDekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

10.QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11.Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12.Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.

13.Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T))

Course Objective:

- To develop Comprehensive Knowledge in Pharmaceutical Quality Systems.
- To Prepare Students for Effective Compliance with Regulatory Standards.
- To Equip Students with Practical Skills in Pharmaceutical Production and Documentation

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Demonstrate*** the ability to apply Quality Control and Assurance principles in pharmaceutical manufacturing, ensuring compliance with GLP, GMP, and international standards..	PO1, PO2, PO3,PO7, PO12
CO-2	**Implement** cGMP guidelines (Schedule M, USFDA, WHO, EMEA) and ensure regulatory compliance across pharmaceutical manufacturing processes.	PO1, PO2, PO3,PO7, PO12
CO-3	***proficient*** in analyzing raw materials, in-process products, and finished goods, with the ability to develop and apply specifications according to pharmacopoeia standards.	PO1, PO2, PO3, PO12
CO-4	**Create and manage** essential documentation in the pharmaceutical industry, including SOPs, Master Formula Records, batch records, and audit reports, ensuring accurate and compliant record-keeping.	PO1, PO2, PO3, PO12
CO-5	***Implement*** manufacturing processes, ensuring quality control in production, packaging, sanitation, aseptic techniques, and change control procedures, contributing to safe and compliant drug manufacturing**.**	PO1, PO2, PO3, PO12

THEORY **60 Hours**

1. 12 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.

2. 12 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.

3. 12Hrs

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.

4. 12 Hrs

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

6. 12 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.

REFERENCES

1.Pharmacognosy by Trease and Evans

2.Pharmacognosy by Kokate, Purohit and Gokhale

3.Quality Control Methods for Medicinal Plant, WHO, Geneva

4.Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar

5. Essential of Pharmacognosy by Dr.S.H.Ansari

6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd.,

7. Indian Standard specification, for raw materials, BIS, New Delhi.

8.Indian Standard specification for 28 finished cosmetics BIS, New Delhi

9.Harry's Cosmeticology 8th edition

10.Suppliers catalogue on specialized cosmetic excipients

11.Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps

12.Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

PHARMACEUTICAL ANALYSIS PRACTICAL – II (MPA 205P)

Course Objective:

- To Equip Students with Analytical Techniques for Organic Compound Identification
- To Develop Expertise in Bioanalytical and Pharmaceutical Testing.
- To Provide Practical Knowledge in Quality Control of Pharmaceutical Products.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Able*** to interpret absorption spectra of organic compounds using UV and apply the Woodward-Fieser rule to predict absorption maxima, facilitating structure elucidation..	PO1, PO2, PO3,PO4, PO12
CO-2	***Able*** to conduct quality control tests for tablets, capsules, parenterals, creams, and raw materials, including the determination of impurities and related substances according to pharmacopeial standards.	PO1, PO2, PO3,PO4, PO12
CO-3	***Develop*** the skills to accurately interpret FT-IR, NMR, and Mass Spectra data for identifying functional groups and structural features of organic compounds.	PO1, PO2, PO3,PO4, PO12
CO-4	***Gain*** the ability to separate biomolecules using gel electrophoresis and HPLC, while performing quantitative analysis of bioactive components in biological fluids and samples.	PO1, PO2, PO3,PO4, PO12
CO-5	***Prepare*** essential documents such as Master Formula Records, Batch Manufacturing Records, and validation protocols for analytical methods and bioanalytical studies, ensuring compliance with regulatory requirements	PO1, PO2, PO3,PO4, PO12

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 Massspectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).

10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In-process and finished product quality control tests for tablets, capsules, parenteral and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

SEMESTER-III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM301T)

Course Objective:

- To provide value addition and current requirement in clinical research and pharmacovigilance
- To conceptualizing, designing, conducting, managing and reporting of clinical trials.
- To develop drug safety data in Pre-clinical and clinical phases of Drug development and post-market surveillance.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** the regulatory requirements for conducting clinical trial	PO1, PO2,PO3, PO7, PO12
CO-2	***Demonstrate*** the types of clinical trial designs	PO1, PO2,PO3, PO7, PO12
CO-3	***Execute*** safety monitoring, reporting and close-out activities	PO1, PO2,PO3, PO7, PO12
CO-4	***Describe*** the principles of Pharmacovigilance	PO1, PO2,PO3, PO7, PO12
CO-5	***Perform*** the adverse drug reaction reporting systems and communication in Pharmacovigilance	PO1, PO2,PO3, PO7, PO12

THEORY **60 Hours**

12 Hrs

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

12Hrs

2.Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

12 Hrs

3.Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

12 Hrs

4.CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

12 Hrs

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

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CAMPUSES:

Paralakhemundi Campus
Village Alluri Nagar
P.O. – R Sitapur, Via- Uppalada
Paralakhemundi, Dist.- Gajapati
Odisha, India. PIN– 761211

Bhubaneswar Campus
Ramchandrapur
P.O. – Jatni, Bhubaneswar
Dist.- Khurda, Odisha,
India, PIN– 752050

Balangir Campus
Behind BSNL Office
IDCO land, Rajib Nagar
Dist.- Balangir, Odisha
India, PIN-767001

Rayagada Campus
IDCO Industrial Area
Pitamahal, Rayagada
Dist.-Rayagada, Odisha
India, PIN-765001

Balasore Campus
Gopalpur,
P.O.-Balasore
Dist.-Balasore, Odisha
India, PIN-756044

Chatrapur Campus
Ramchandrapur,
Kaliabali Chhak,
P.O-Chatrapur, Dist.-Ganjam
Odisha, India, PIN-761020