ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2. Every student, selected for admission to PG 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.

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance 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.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes 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

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, 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 below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 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:

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

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 AB grade awarded in that semester. For example if a learner has F or AB grade in course 4, the SGPA shall then be computed as:

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

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. 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:

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

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 1: Pharmaceutical Analysis (MPA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPA 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPA 102T	Advanced Pharmaceutical Analysis	4	4	10	20	30	70	100
MPA 103T	Pharmaceutical Validation (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MPA 104T	Food Analysis	4	4	10	20	30	70	100
MPA 105P	Pharmaceutical Analysis Practical - I	2	6	15	15	30	70	100
MPA 106P	Pharmaceutical Analysis Practical - II	2	6	15	15	30	70	100
MPA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPA 201T	Advanced Instrumental Analysis	4	4	10	20	30	70	100
MPA 202T	Modern Bio-Analytical Techniques	4	4	10	20	30	70	100
MPA 203T	Quality Control and Quality Assurance (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MPA 204T	Herbal and Cosmetic Analysis	4	4	10	20	30	70	100
MPA 205P	Pharmaceutical Analysis Practical - III	2	6	15	15	30	70	100
MPA 206	Comprehensive Viva	2	---	---	---	---	---	50
MPA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 1: Pharmaceutical Analysis (MPA) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPA 302	Journal Club*	2	2	50	---	---	---	50
MPA 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPA 304	Seminar on selected topic	4	4	---	---	---	100	100
MPA 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPA 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPA 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPA 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

PHARMACEUTICAL ANALYSIS (MPA)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. 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.

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, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 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 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

a. 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 methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

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

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Unit 1:

Impurities and stability studies: Definition, classification of impurities in drug substance or active pharmaceutical ingredients and quantification of impurities as per ICH guidelines – Q3A & Q3D. 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.

12 Hours

Unit 2:

Impurity profiling and degradent characterization (ICH Q2A & Q2B): Stability studies accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, stability zones.

Elemental impurities: Basics of impurity profiling and degradent characterization with special emphasis. Method development and concepts of validation. 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. (Ref: USP 38 NF 33, Vol. I, 2015, Chapter 232 & 233). **14 Hours**

Unit 3:

Stability testing protocols (ICH Q1A): 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. Photostability testing guidelines, ICH stability guidelines for biological products (ICHQ5C).

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. **12 Hours**

Unit 4:

Biological tests: Preservative challenging test, disinfectant efficacy test and its validation. Neutralizer efficacy test, membrane filter integrity test, bacterial endotoxin test & microbial limit test. Container–closure integrity test for sterile products. **12 Hours**

Unit 5:

Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA (ELISA), Fluoro IA, Luminescence IA, Quantification and applications of IA. **10 Hours**

REFERENCES

1. Vogel's Textbook of Quantitative Chemical Analysis - Jeffery J Bassett, J. Mendham, R. C. Denney. 5th ed. ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake. Vol 2, 4th ed. CBS Publishers, New Delhi.
3. Textbook of Pharmaceutical Analysis – K.A. Connors. 3rd ed. John Wiley & Sons, 1982
4. Pharmaceutical Analysis - Higuchi, 2nd ed. Wiley – Inter Science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi, 3rd ed. CBS Publishers, New Delhi.
6. Pharmaceutical Analysis- Modern Methods – J.W. Munson – Part B. Volume 11, Marcel Dekker.
7. The Quantitative Analysis of Drugs – D.C. Carratt. 3rd ed. CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia 2007, 2010, 2014 & 2018.
9. Methods of Sampling and Microbiological Examination of Water, First Revision, BIS
10. Analytical Profiles of Drug Substances – Klaus Florey. Vol 1 – 20, Elsevier, 2005
11. Analytical Profiles of Drug Substances and Excipients – Harry G Brittain. Volume 30, Elsevier, 2005.
12. The Analysis of Drugs in Biological Fluids - Joseph Chamberlain. 2nd ed. CRC Press,
13. ICH Guidelines for Impurity Profiles and Stability Studies

PHARMACEUTICAL VALIDATION (MPA 103T)

(Note: Common paper for MPA and MQA specializations)

Unit 1:

Introduction to validation: Definition of calibration, qualification and validation, scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of validation, scope of validation, organization for validation, validation master plan, types 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). **12 Hours**

Unit 2:

Qualification of analytical instruments/Equipment: Training & qualification of analyst. qualification of UV-visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, and dissolution test apparatus. **10 Hours**

Unit 3:

Validation of utility systems: Pharmaceutical water system, HVAC system, compressed air and nitrogen. Facility qualification, AHU validation, clean room validation.

Cleaning validation: Cleaning method development, sampling techniques, validation of analytical method used in cleaning. Cleaning of equipment, cleaning of facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5, LIMS, audit trail and data integrity. **12 Hours**

Unit 4:

Process validation: Concept, process and documentation of process validation. Prospective, concurrent & retrospective validation, re validation criteria, process validation of various formulations (coated tablets, capsules, ointment/creams, liquid orals and aerosols).

Aseptic filling: Media fill validation, USFDA guidelines on process validation- A life cycle approach.

Analytical method validation: General principles, validation of analytical method as per ICH guidelines (Q2A) and USP. Preparation & qualification of working standards and reference standards. **12 Hours**

Unit 5:

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 application; patent application forms and guidelines. Types of 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 of technology (TOT), IP and ethics-positive and negative aspects of IPP; societal responsibility, avoiding unethical practices. **14 Hours**

REFERENCES

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

9. Validation Master Plan - Terveeks or Deeks. Davis Harwood International Publishing.

FOOD ANALYSIS (MPA 104T)

Unit 1:

Carbohydrates: Classification and properties of food carbohydrates, general methods of analysis of food carbohydrates, changes in food carbohydrates during processing, digestion, absorption and metabolism of carbohydrates. Dietary fiber, crude fiber 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. **12 Hours**

Unit 2:

Lipids: Classification, general methods of analysis, determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: Classification of vitamins, principle & microbial assays of vitamin-B_1, B_2 & B_{12}. **12 Hours**

Unit 3:

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. **12 Hours**

Unit 4: 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. **12 Hours**

Unit 5:

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. FSSAI guidelines-special emphasis on mycotoxins, microbiology, antibiotic residues in foods. HACCP (Biological, Physical & Chemical hazards), Regulatory aspects of CODEX Alimentarius. **12 Hours**

REFERENCES

1. The Chemical Analysis of Foods – David Pearson. 7th ed. 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. 6th ed. Volume 1 & 2. 1997.
4. Analysis of Food Constituents – Multon. John Wiley & Sons.
5. Official methods of analysis of AOAC International - Dr. William Horwitz. 18th ed. 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL - I (MPA 105P)

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

PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 106P)

1. Calibration of glassware
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of FTIR spectrophotometer
5. Calibration of GC instrument
6. Calibration of HPLC instrument
7. Cleaning validation of any one equipment
8. Determination of total reducing sugar
9. Determination of proteins
10. Determination of saponification value, iodine value, peroxide value, acid value in food products
11. Determination of fat content and rancidity in food products
12. Analysis of natural and synthetic colors in food
13. Determination of preservatives in food
14. Determination of pesticide residue in food products
15. Analysis of vitamin content in food products
16. Determination of density and specific gravity of foods
17. Determination of food additives.
18. Analysis of vanillin content in foods
19. Analysis of oxalate content in guava fruit
20. ELISA & CLIA – demonstration
21. IMVIC test - Indole test, methyl red test, Voges-Proskauer test, citrate utilization test

Second Semester

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Unit 1:

HPLC: Principle, analytical method development, 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, and preparative HPLC in pharmaceutical analysis. Advancement in enantiomeric separations, Immobilized polysaccharide CSP's and HILIC approaches. **12 Hours**

Unit 2:

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

Gas chromatography: Derivatization, head space sampling, analytical method development and quantification. **12 Hours**

Unit 3:

Super critical fluid chromatography: Principle, instrumentation, pharmaceutical applications.

Capillary electrophoresis: General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation & its applications.

12 Hours

Unit 4:

Mass spectrometry: LC-MS hyphenation and DART MS analysis. Mass analyzers (Quadrupole, 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. **12 Hours**

Unit 5:

NMR spectroscopy:

Brief outline of principles of NMR &FT-NMR. Spin-spin and spin-lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, interpretation and qualitative and quantitative applications of NMR spectroscopy. LC-NMR hyphenations. ICP-MS, ICP-OES, PES, TOC Analysis, KF titration, melting point determination using advanced instrumentation. **12 Hours**

REFERENCES

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Organic Spectroscopy - William Kemp. 3rd ed. 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 ed. CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern Methods – Part B – J.W. Munson. Vol 11, Marcel Dekker Series.
8. Organic Spectroscopy - Donald L Paviya. 5th ed.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Unit 1:

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. **12 Hours**

Unit 2:

Biopharmaceutical consideration: Introduction, in vitro: dissolution and drug release

testing, alternative methods of dissolution testing. Solubility: experimental methods. permeability: in-vitro, in-situ and in-vivo methods. **12 Hours**

Unit 3:

Pharmacokinetics and toxicokinetics: Basic consideration, drug interaction (PK-PD interactions), the effect of protein-binding interactions, the effect of tissue-binding interactions, toxicokinetics-toxicokinetic evaluation in preclinical studies, importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

12 Hours

Unit 4:

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. **12 Hours**

Unit 5:

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. **12 Hours**

REFERENCES

1. Analysis of Drugs in Biological Fluids - Joseph Chamberlain. 2nd ed. CRC Press.
2. Principles of Instrumental Analysis - Doglas A Skoog. 5th ed. Eastern Press, Bangalore.
3. Pharmaceutical Analysis - Higuchi, Brochmman & Hassen. 2nd ed. Wiley Interscience
4. Pharmaceutical Analysis - Modern methods – Part B – J.W. Munson. Vol 11, Marcel Dekker.
5. Practical HPLC Method Development – Snyder & Kirkland. 2nd ed. John Wiley & Sons.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics. 2nd ed. Marcel Dekker.
7. Chromatographic Methods in Clinical Chemistry & Toxicology – Roger L Bertholf & Ruth E Winecker. John Wiley & Sons, New Jersey, USA, 2007.
8. Good Laboratory Practice Regulations - Sandy Weinberg. Vol. 69. 2nd ed. Marcel Dekker.
9. Good laboratory Practice Regulations – Allen F. Hirsch. Vol. 38. Marcel Dekker, 1989.
10. ICH, USFDA & CDSCO Guidelines.

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

(Common paper for MPA and MQA specializations)

Unit 1:

Introduction: 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.

CPCSEA guidelines: Control on animal house, report preparation and documentation.

12 Hours

Unit 2:

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, clean room validation, control of contamination, sterility assurance, AHU system & qualification, and Good Warehousing Practice. **12 Hours**

Unit 3:

Developing specification (ICH Q6 and Q3), sampling methods for raw and packing materials. Purchase specifications, vendor qualification and maintenance of stores for various materials.

Testing of primary packing materials as per IP & USP: Glass containers, plastics, rubber.

Analysis of raw materials, packaging materials: In-process quality control and finished products quality control for following formulations in pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products. Quality control test for containers, closures and secondary packing materials. **12 Hours**

Unit 4:

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 Manufacturing Record, quality audit plan and reports. Specification and test procedures, protocols and reports. distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). **12 Hours**

Unit 5:

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. **12 Hours**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India. 3rd Revised ed. Vol 1 & 2, Mumbai, 1996.
2. Good Laboratory Practice Regulations - Sandy Weinberg. Vol. 69. 2nd ed. Marcel Dekker.
3. Quality Assurance of Pharmaceuticals - A compendium of Guidelines and Related Materials. Vol 1 & 2. 2nd ed. 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, Excipients and Dosage forms, 3rd ed. WHO, Geneva, 2005.
6. Good Laboratory Practice Regulations – Allen F Hirsch. Vol 38. Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and Total Quality Management

9. The Drugs and Cosmetics Act 1940 – Deshpande & Nilesh Gandhi. 4th ed. Susmit Publishers.
10. QA Manual – D.H. Shah 1st ed. Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals; A Plan for Total Quality Control – Sidney H. Willig. Vol. 52. 3rd ed. Marcel Dekker.
12. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers - Steinborn L (Volume 1 - With Checklists and Software Package). 6th ed. Taylor & Francis.
13. Quality Systems and Controls for Pharmaceuticals – D.K. Sarker. John Wiley & Sons, 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Unit 1:

Herbal remedies: Toxicity and regulations: Herbals vs. conventional drugs, Efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamics and pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

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. **12 Hours**

Unit 2:

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.

12 Hours

Unit 3:

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, adulterant screening using modern analytical instruments, 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, WHO guidelines in quality assessment of herbal drugs.

12 Hours

Unit 4:

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. **12 Hours**

Unit 5:

Evaluation of cosmetic products: Determination of 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.

Schedule S: Standards for cosmetics. 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. **12 Hours**

REFERENCES

1. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy - Kokate, Purohit & Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy & Pharmacobiotechnology - Ashutosh Kar.
5. Essential of Pharmacognosy - S.H.Ansari.
6. Cosmetics – Formulation, Manufacturing and Quality Control - P.P. Sharma. 4th ed. Vandana Publications Pvt. Ltd., Delhi.
7. Indian Standard Specification for Raw Materials, BIS, New Delhi.
8. Indian Standard Specification for 28 Finished Cosmetics BIS, New Delhi.
9. Harry's Cosmeticology. 8th ed.
10. Suppliers Catalogue on Specialized Cosmetic Excipients.
11. Poucher's Perfumes, Cosmetics & Soaps – Hilda Butler. 10th ed. Kluwer Academic Publishers.
12. Handbook of Cosmetic Science and Technology. 3rd ed.

PHARMACEUTICAL ANALYSIS PRACTICAL - III (MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward - Fiesure rule
2. Interpretation of organic compounds by FTIR
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 FTIR, NMR, CNMR and mass spectra
7. In process and finished product quality control tests for tablets, capsules, parenterals and creams
8. Quality control tests for primary and secondary packing materials
9. Assay of raw materials as per official monographs
10. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by gel electrophoresis.
11. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by HPLC techniques
12. Isolation of analgesics from biological fluids (blood, serum and urine)
13. Protocol preparation and performance of analytical/bio analytical method validation
14. Protocol preparation for the conduct of BA/BE studies according to guidelines
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

A.U. COLLEGE OF PHARMACEUTICAL SCIENCES

M. Pharm – Pharmaceutical Analysis

Program outcomes

The program outcomes for the Master of Pharmacy Program at various specializations are framed based on outputs and opinions from various stakeholders who are relevant to this program.

After successful completion of program, the student will be able to

PO:01 Handle a variety of advanced instrumental techniques like HPLC, UPLC, and GC for drug identification, characterization, and quantification.

PO:02 Understand the science of impurity detection, impurities in pharmaceutical formulations, impurity profiling, phytopharmaceutical stability testing, and protocol development.

PO:03 Fetch content on validation and its application in industry, their methodologies, and their application in manufacturing processes.

PO:04 Impart knowledge on food constituent and finished food product analysis and quantification, food additives, pesticides, food regulations, and food product legislation.

PO:05 Learn about Intellectual property rights that helps them to become future entrepreneurs.

PO:06 Gain knowledge of a variety of hyphenated analytical instrumental techniques for drug and herbal analysis, characterization, and quantification.

PO:07 Apprehend the process of drug extraction and separation from biological samples using various techniques, as well as analytical method guidelines.

PO:08 Know the pharmaceutical industry quality assurance aspects such as CGMP,

documentation, certifications, GLP, and other regulatory affairs.

PO:09 Develop a talent pool by involving students in journal clubs, research projects and requiring students to conduct research projects under faculty supervision for publication.

PO:10 Pursue higher education and career advancement through MOOCS courses that explores inter disciplinary research.

PROGRAM EDUCATIONAL OBJECTIVES

1. To provide an in depth analytical and advanced pharmaceutical education leading to M. Pharm. Degree specialization
2. To combine pharmacy knowledge and analytical skills with pharmaceutical field
3. To nurture pharmacists and research analysts to contribute effectively in the social health care system
4. To provide hands on training to impart analytical knowledge and research aptitude in pharmaceutical sciences
5. To inculcate leadership and entrepreneurship capabilities in future pharmacy professionals

PROGRAM SPECIFIC OUTCOMES (PSOs)

1. Able to apply the knowledge gained during the course from various subjects like Modern pharmaceutical analytical techniques, Quality control and Quality assurance, Modern bioanalytical techniques, Advanced instrumental analysis and Herbal and cosmetic analysis.
2. Able to inculcate the knowledge of ethical and leadership in diverse situations of patient health care
3. Able to carryout research in their respective analytical field with the knowledge gained through Biostatistics and Research methodology
4. Able to do profuse jobs in the pharmaceutical industries through analytical skills and to write effective project reports in view of changing technologies

5. Able to communicate and perform multitasks in multi fields including pharmaceutical, herbal & cosmetics research areas

M. Pharm Course outcomes

MPA 101T Modern pharmaceutical analytical techniques

Course outcomes:

After completing the course, the student will

1. Acquire knowledge on variety of spectroscopic methods, including IR, UV-visible, Spectrofluorimetric, Flame emission and Atomic absorption spectroscopy and their uses in pharmaceutical analysis
2. Be aware of NMR spectroscopy interpretation and structural elucidation of different substances
3. Gain enviable skills on Mass spectroscopy ionization methods and different fragmentation patterns
4. Become familiar over Chromatographic techniques: a variety of applications and data interpretation
5. Understand the usage of thermal, microscopic, X-ray crystallography and electrophoretic methods in medicinal applications

MPA 102T Advanced Pharmaceutical Analysis

Course outcomes:

After completing the course, the student will

1. Study on impurities and stability studies; impurities in residual solvents and the extent of their reporting
2. Be educated with ICH-recommended elemental impurity categorization, degradant characterization and impurity profiling

3. Acquire information related to ICH-mandated stability testing procedures and phytopharmaceutical stability testing
4. Develop skills in range of biological assays for sterile goods
5. Perform Immunoassay (IA) quantification and application studies

MPA 103T Pharmaceutical Validation

Course outcomes:

After completing the course, the learner will be capable in

1. Acquiring knowledge on types and concepts of specifications for validation, calibration and qualification
2. Accreditation of diverse analytical tools and apparatus
3. Dealing with computerized system validation for data integrity, utility system validation and cleaning validation studies are explained
4. Involving studies like aseptic filling, analytical method validation in accordance with ICH and process validation
5. Developing fundamental ideas pertaining to intellectual property rights are explained

MPA 104T Food Analysis

Course outcomes:

After completing the course, the learner will

1. Study general techniques for analyzing the proteins, carbs and amino acids in foods
2. Have skills in general techniques, identifying and analyzing lipid adulterants and vitamins
3. Gain knowledge in examination of artificial sweeteners, pigments, artificial colors, antioxidants and preservatives in foods
4. Developed skills about analytical techniques for analyzing milk, its components and its products, as well as fermentation products such as vinegar, wine, spirits and beer
5. Gain knowledge on analysis of pesticides and their regulatory aspects

MPA 105 Pharmaceutical Analysis Practical-I

Course outcomes:

After completing the course, the learner will be able to obtain knowledge about

1. UV-Visible spectrophotometer analysis of pharmacopeial compounds and their formulations
2. Pharmacokinetic analysis using various reagents
3. Handling instruments such as Flame photometers, Fluorimeters, UV, HPLC and GC
4. Drug quantification using a variety of analytical methods
5. Conducting experiments on impurity profiling

MPA 106P Pharmaceutical Analysis Practical – II

Course outcomes:

After completing the course, the learner will be able

1. To gain enough knowledge in handling Glassware, pH meters, UV, HPLC, GC, Flame photometers, Fluorimeters and FTIR calibration and validation
2. Perform qualitative and quantitative examination of the fats, proteins and carbohydrates
3. Measure food products fat content and rancidity as well as examining their natural and artificial coloring
4. To give thorough explanation and process for performing bioassays
5. Perform tests, IMVIC tests: Citrate utilization test, Voges-Proskauer test, Methyl red test and Indole test

MPA 201T Advanced Instrumental Analysis

Course outcomes:

After completing the course, the student will be able to comprehend

1. The fundamentals of analytical method development and the applications of HPLC in pharmaceuticals

2. Different forms of Bio chromatography and the uses of biotechnology in medicine
3. Pharmaceutical applications, instrumentation and Supercritical fluid chromatography
4. Overarching ideas and technique are developed in advancement in Mass spectrometry, hyphenated LC-MS, and DART-MS analysis
5. Skills in NMR & FT Principles: NMR interpretation, LC-NMR hyphenations and qualitative and quantitative applications of NMR Spectroscopy

MPA 202T Modern Bio-Analytical Techniques

Course outcomes:

After completing the course, the students are capable to perform

1. Drug and metabolite extraction from biological matrices and validation of bioanalytical methods
2. Experiments in Biopharmaceutics
3. Studies in pharmacokinetic and toxicokinetic interactions, as well as drug screening implications
4. Studies for identification of metabolites, protocols, in-vitro/in-vivo techniques and sample preparation techniques
5. Studies on the effectiveness of drug products, the goal of studies on bioavailability and bioequivalence, and the clinical importance of these findings

MPA 203T Quality Control and Quality Assurance

Course outcomes:

After completing the course, the student will be familiar to comprehend the following

1. Concepts and development of quality assurance and control, Good Laboratory Practices and GMP and CPCSEA guidelines
2. cGMP guidelines in accordance with schedule M, the guidelines to be followed in sterile areas by the WHO, EMEA, USFDA (including CDER and CBER), and the

Pharmaceutical Inspection Convention (PIC)

3. Techniques for sampling raw and packaged materials. Specifications for purchases, evaluation of vendors and upkeep of storage facilities for various materials. Primary packing material testing in accordance with IP and USP
4. Abilities in fundamentals of documentation in the pharmaceutical industry, including records and formats
5. Operations related to manufacturing, bulk products, intermediate controls and packaging

MPA 204T Herbal and Cosmetic Analysis

Course outcomes:

After completing the course, the student will be able to

1. Attain knowledge in the standardization of herbal drugs, the guidelines set forth by the WHO and AYUSH and the regulatory requirements that govern the herbal drug industry
2. Understand microbial contamination, deterioration and indulgence in herbal formulations
3. Gain information in testing medications and natural products
4. Discuss the difficulties in ensuring the safety of herbal medications and the potential for drug interactions
5. Perform Cosmetic product evaluation tests

MPA 205P Pharmaceutical Analysis Practical–III

Course outcomes

After completing the course, the student will gain practical knowledge in

1. Interpretation and structural elucidation of compound by UV, FTIR, NMR and Mass spectroscopic techniques

2. Documentation and performing tests for quality control
3. Preparing protocols in accordance with guidelines to conduct BA/BE studies
4. Separation of biomolecules using different sample preparation methods and quantitative component analysis using HPLC methods
5. Maintaining the Batch and Master Formula Records