

MAHARAJAH'S COLLEGE OF PHARMACY

Approved to AICTE, PCI, New Delhi; Affiliated to Andhra University, Vsp

Accredited by NBA

Phool baugh, Vizianagaram - 535002



MASTER OF PHARMACY Pharmaceutical Analysis

Regulations and Syllabus

RULES AND REGULATIONS

The educational institutions established by the MANSAS are well known for imparting value based education. MANSAS has formulated the following rules to be followed by the candidates admitted in to the **Maharajah's College of Pharmacy**.

Every student admitted to Maharajah's College of Pharmacy, Vizianagaram is advised to read carefully the following rules of admission conduct and adhere to the same. Failure to comply with them may result in forfeiting of provisional admission, without any refund of fee.

- 1) Every student who is granted a provisional admission to a Pharmacy course in the college by University/APSCHE/ management shall report to the college office within stipulated period from the date of allotment of seat, failing which his/her admission is deemed to be cancelled without any refund of fee.
- 2) The student should submit the following original certificates along with two sets of Xerox copies to the college office at the time of admission. SSC Certificate, Intermediate or 10+2 Pass Certificate, EAMCET Rank card, Study and Conduct Certificate for the last seven years of the qualifying examination, Transfer certificate from the institution where the candidate last studied for the qualifying examination, Integrated community certificate issued by the competent authority in case of BC/SC/ST candidates in due proforma as prescribed by the Government of A.P., Xerox copy of Ration card and Aadhar card and Four recent passport size photos and stamp size each.
- 3) The college will retain the original certificates in case of scholarship holders, till the completion of Pharmacy course or exit of the candidate on T.C. whichever is earlier.
- 4) The original certificates deposited in the college office will not be issued to the candidate for any reason what so ever. If the students want to discontinue his studies, he/she shall have to pay all the college fee upto the year of study as prescribed by the Management, for obtaining any certificate from the College.
- 5) The college works from 9 AM to 4 PM on all six working days of a week, with a lunch break from 12-30 PM to 1-30 PM.
- 6) The students shall pay the **fees** stipulated by the college office from time to time as per schedule. **Outgoing students shall be issued transfer certificate only on clearance of all dues and fines** if any, relating to the concerned sections, college office, library, and hostel.
- 7) Students under semester system shall clear tuition fees payable to the college before commencement of every semester on the date prescribed by college. Fee defaulters will not be allowed to attend classes/labs/library and lose their attendance, without any notice thereto.
- 8) If the Government reimburses part of the tuition fee and special fee to the scholarship holders, the difference of the fee shall be remitted by the student, failing which, T.C and other original certificates will be withheld by the college. **In case no fee reimbursement is made by the Government in time, the candidate has to pay all fees, dues and then apply for T.C.** The Management in no way is responsible for reimbursement of fee by the Government of A.P.
- 9) The College reserves every right to refrain from issuing T.C to any of its students or take a deserving action, if his/her behavior is against the code of conduct.
- 10) Students admitted under spot or management quota are not eligible to apply for scholarships and the college will not forward such applications.

- 11) Every student shall put in 75% of minimum attendance during all months of class work. **No student having attendance below 75% will be allowed for the university examinations.** Any Student, who does not put in the required attendance, shall repeat the course next year, by paying complete fees again, after obtaining readmission from the Andhra University.
- 12) Every student shall participate in seminar/ symposia/ work shop/ conference or any such academic activity conducted by college, for which some credits are offered in the curriculum.
- 13) Every student is expected to wear identity card issued by the college in the premises for verification by security or college authorities or library.
- 14) Students and staff are requested to switch off lights and fans, as and when not necessary.
- 15) Every student should attend the college in a neat uniform or dress and apron for the laboratory
- 16) **Ragging is prohibited within or outside of educational institution as per Proc.dt.10-10-2016.**
- 17) The student shall confine themselves to class rooms/labs during working hours. No student is allowed to loiter on corridors /verandahs of the college or canteen without proper reason.
- 18) Any student who misbehaves in the class room/campus is liable to be expelled the college, following the decision of the Discipline Committee.
- 19) A limited Hostel accommodation is provided by the college separate for men and women, on first come first served basis. A student who is allotted hostel accommodation shall remit Rs.10,000/- as an advance and clear the monthly mess bills on stipulated date. Scholarship holders shall also pay the advance and monthly bills as per schedule and the amount will be reimbursed to them on receipt of such amounts from the government. All the hostel inmates should follow rules and regulations as prescribed by the management and no student is permitted to leave the hostel without prior approval of the concern.
- 20) Use of mobile phones on college campus by students is strictly forbidden and a fine of Rs.500 will be levied, if found using such. The mobile will also be confiscated.
- 21) Cycles, motor cycles or such two wheelers etc., shall only be parked in the places provided for them.
- 22) Students who are punished by police, university authorities for indulging in any type of malpractices etc., are liable to be dismissed from college and under no circumstances they will be given readmission. The college has the power to hold the conduct certificate of such a student, if recommended by the Discipline Committee.
- 23) Any student who is found to have obtained admission into this college by any false representation of facts is liable to be dismissed and forfeits his admission as well as fee paid thereof.
- 24) A student who wishes to leave the college for any reasons in the middle of the academic year is not entitled for any refund of fee. Further, he/she shall have to clear all dues before obtaining his T.C and other certificates.
- 25) The management of the college has the right to take cognizance of the offense on the part of a student even outside the college campus.
- 26) No student of the college is permitted to participate in any direct or indirect political activity detrimental to the peaceful academic atmosphere of the college and its premises.
- 27) The management of the MANSAS has the right to amend the above said rules from time to time if necessary, in the interest of imparting quality education to its students.

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance
2. Examinations - Sessional and Semester - end
3. Eligibility criteria for appointment as examiner for M.Pharm examination
4. Regulations for pursuing M.Pharm III and IV Semester project
5. Declaration of results and classification:
6. Grading system:
7. Guidelines for paper setting and model papers.

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 consist 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 sessionals. 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 incompleteness.
- 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:

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

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:

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

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:

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

Where C₁,C₂,C₃, 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 10: Pharmacy Practice (MPP) continued

| III Semester | | | | | | | | |
|---------------------|---|-----------|-----------|-----|-----|-----|-----|------------|
| MRM 301T | Research Methodology and Biostatistics* | 2 | 4 | 10 | 20 | 30 | 70 | 100 |
| MPP 302 | Journal Club* | 2 | 2 | 50 | --- | --- | --- | 50 |
| MPP 303 | Discussion /Presentation (Dissertation Title & Project Proposal)* | 2 | --- | 50 | --- | --- | --- | 50 |
| MPP 304 | Seminar on selected topic | 4 | 4 | --- | --- | --- | 100 | 100 |
| MPP 305 | Research Work Progress (Mid Term Report) | 10 | 20 | --- | --- | --- | 200 | 100 |
| | Total: | 20 | 30 | --- | --- | --- | --- | 400 |
| IV Semester | | | | | | | | |
| MPP 401 | Journal Club* | 2 | 2 | 50 | --- | --- | --- | 50 |
| MPP 402 | Thesis evaluation | 12 | 20 | --- | --- | --- | 150 | 150 |
| MPP 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. Spectrofluorimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by fluorimetry), 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. **10 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 - Douglas 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 degradant 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 degradant 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-B₁, B₂ & B₁₂. **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-D and 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 - Douglas 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 - Douglas 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

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 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. **12 Hours**

Unit 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 (Wilcoxon rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net