# V. V. INSTITUTE OF PHARMACEUTICAL SCIENCES

Seshadri Rao Knowledge Village, Gudlavalleru - 521 356

(Approved by AICTE & PCI, New Delhi and Affiliated to JNTUK, Kakinada)

# ACADEMIC REGULATIONS
# COURSE STRUCTURE
# AND
# DETAILED SYLLABUS
# FOR
# M. PHARMACY

## *Pharmaceutical Analysis*

*(with effect from 2018-19)*

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA

KAKINADA - 533003, ANDHRA PRADESH, INDIA.

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## PHARMACY COUNCIL OF INDIA

### NOTIFICATION

New Delhi, the 10th December, 2014

### The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

# CHAPTER –I: REGULATIONS

## 1. Short Title and Commencement

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

## 2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

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

## 3. Duration of the program

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

## 4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

## 5. Working days in each semester

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

## 6. Attendance and progress

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

## 7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

### 7.1. Credit assignment

#### 7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

### 7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

## 8. Academic work

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

## 9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

| S. No. | Specialization | Code |
|---|---|---|
| 1. | Pharmaceutics | MPH |
| 2. | Industrial Pharmacy | MIP |
| 3. | Pharmaceutical Chemistry | MPC |
| 4. | Pharmaceutical Analysis | MPA |
| 5. | Pharmaceutical Quality Assurance | MQA |
| 6. | Pharmaceutical Regulatory Affairs | MRA |
| 7. | Pharmaceutical Biotechnology | MPB |
| 8. | Pharmacy Practice | MPP |
| 9. | Pharmacology | MPL |
| 10. | Pharmacognosy | MPG |

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table – 5: Course of study for M. Pharm. (Pharmaceutical Analysis)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| Semester I | | | | | |
| MPA101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPA102T | Advanced Pharmaceutical Analysis | 4 | 4 | 4 | 100 |
| MPA103T | Pharmaceutical Validation | 4 | 4 | 4 | 100 |
| MPA104T | Food Analysis | 4 | 4 | 4 | 100 |
| MPA105PA | Pharmaceutical Analysis Practical I | 6 | 3 | 6 | 75 |
| MPA105PB | Pharmaceutical Analysis Practical II | 6 | 3 | 6 | 75 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPA201T | Advanced Instrumental Analysis | 4 | 4 | 4 | 100 |
| MPA202T | Modern Bio-Analytical Techniques | 4 | 4 | 4 | 100 |
| MPA203T | Quality Control and Quality Assurance | 4 | 4 | 4 | 100 |
| MPA204T | Herbal and Cosmetic Analysis | 4 | 4 | 4 | 100 |
| MPA205PA | Pharmaceutical Analysis Practical III | 6 | 3 | 6 | 75 |
| MPA205PB | Pharmaceutical Analysis Practical IV | 6 | 3 | 6 | 75 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | Total | 35 | 26 | 35 | 650 |

Table – 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| MRM301T | Research Methodology and Biostatistics* | 4 | 4 |
| - | Journal club | 1 | 1 |
| - | Discussion / Presentation (Proposal Presentation) | 2 | 2 |
| - | Research Work | 28 | 14 |
| Total | | 35 | 21 |

* Non University Exam

Table – 13: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

| Course Code | Course | Credit Hours | Credit Points |
|---|---|---|---|
| - | Journal Club | 1 | 1 |
| - | Research Work | 31 | 16 |
| - | Discussion/Final Presentation | 3 | 3 |
| Total | | 35 | 20 |

Table – 14: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

Table – 15: Guidelines for Awarding Credit Points for Co-curricular Activities

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

Note: International Conference: Held outside India; International Journal: The Editorial Board Outside India

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

## 10. Program Committee

The M. Pharm. programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.

The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

Duties of the Programme Committee:

Periodically reviewing the progress of the classes.

Discussing the problems concerning curriculum, syllabus and the conduct of classes.

Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

1. Communicating its recommendation to the Head of the Institution on academic matters.
2. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

## 11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given from Table–16.

### 11.1. End semester examinations

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

Tables – 16: Schemes for internal assessments and end semester (Pharmaceutics- MPH)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continues Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| **SEMESTER I** | | | | | | | | |
| MPH101T | Modern Pharmaceutical Analytical Techniques | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH102T | Drug Delivery Systems | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH103T | Modern Pharmaceutics | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH104T | Regulatory Affairs | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH105PA | Pharmaceutics Practical I | 10 | 15 | 3Hr | 25 | 50 | 3Hr | 75 |
| MPH105PB | Pharmaceutics Practical II | 10 | 15 | 3Hr | 25 | 50 | 3Hr | 75 |
| - | Seminar/Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | 650 |
| **SEMESTER II** | | | | | | | | |
| MPH201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH203T | Computer Aided Drug Delivery System | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH204T | Formulation Development of Pharmaceutical and Cosmetic Products | 10 | 15 | 1Hr | 25 | 75 | 3Hr | 100 |
| MPH205PA | Pharmaceutics Practical I | 10 | 15 | 3Hr | 25 | 50 | 3Hr | 75 |
| MPH205PB | Pharmaceutics Practical I | 10 | 15 | 3Hr | 25 | 50 | 3Hr | 75 |
| - | Seminar/Assignment | - | - | - | - | - | - | 100 |
| **Total** | | | | | | | | 650 |

## Table - 5 : Course of study for M. Pharm (Pharmaceutical Analysis)

| Course Code | Course | Credit Hours | Credit Points | Hrs. / Wk | Marks |
|---|---|---|---|---|---|
| **SEMESTER - I** | | | | | |
| MPA101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPA102T | Advanced Pharmaceutical Analysis | 4 | 4 | 4 | 100 |
| MPA103T | Pharmaceutical Validation | 4 | 4 | 4 | 100 |
| MPA104T | Food Analysis | 4 | 4 | 4 | 100 |
| MPA105PA | Pharmaceutical Analysis Practical-I | 6 | 3 | 6 | 75 |
| MPA105PB | Pharmaceutical Analysis Practical - II | 6 | 3 | 6 | 75 |
| - | Semister / Assignments | 7 | 4 | 7 | 100 |
| | Total | 35 | 26 | 35 | 650 |
| **SEMESTER - II** | | | | | |
| MPA201T | Advanced Instrumental Analysis | 4 | 4 | 4 | 100 |
| MPA202T | Modem Bio-Analytical Techniques | 4 | 4 | 4 | 100 |
| MPA203T | Quality Control and Quality Assurance | 4 | 4 | 4 | 100 |
| MPA204T | Herbal and Cosmetic Analysis | 4 | 4 | 4 | 100 |
| MPA205PA | Pharmaceutical Analysis Practical - III | 6 | 3 | 6 | 75 |
| MPA205PB | Pharmaceutical Analysis Practical - IV | 6 | 3 | 6 | 75 |
| - | Seminar / Assignment | 7 | 4 | 7 | 100 |
| | TOTAL | 35 | 26 | 35 | 650 |

Tables – 26: Schemes for internal assessments and end semester examinations (Semester III & IV)

| Course Code | Course | Internal Assessment | | | | End Semester Exams | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| | | Continuous Mode | Sessional Exams | | Total | Marks | Duration | |
| | | | Marks | Duration | | | | |
| SEMESTER III | | | | | | | | |
| MRM301T | Research Methodology and Biostatistics* | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| - | Journal club | . | . | . | 25 | . | . | 25 |
| - | Discussion / Presentation (Proposal Presentation) | . | . | . | 50 | . | . | 50 |
| - | Research work* | . | . | . | . | 350 | 1 Hr | 350 |
| Total | | | | | | | | 525 |
| SEMESTER IV | | | | | | | | |
| - | Journal club | . | . | . | 25 | . | . | 25 |
| - | Discussion / Presentation (Proposal Presentation) | . | . | . | 75 | . | . | 75 |
| - | Research work and Colloquium | . | . | . | . | 400 | 1 Hr | 400 |
| Total | | | | | | | | 500 |

*Non University Examination

### 11.2. Internal assessment: Continuous mode

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

Table – 27: Scheme for awarding internal assessment: Continuous mode

| Theory | |
|---|---|
| Criteria | Maximum Marks |
| Attendance (Refer Table – 28) | 8 |
| Student – Teacher interaction | 2 |
| Total | 10 |
| Practical | |
| Attendance (Refer Table – 28) | 10 |
| Based on Practical Records, Regular viva voce, etc. | 10 |
| Total | 20 |

Table – 28: Guidelines for the allotment of marks for attendance

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

#### 11.2.1. Sessional Exams

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

## 12. Promotion and award of grades

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

## 13. Carry forward of marks

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

## 14. Improvement of internal assessment

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

## 15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 29: Tentative schedule of end semester examinations

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

## 16. Allowed to keep terms (ATKT):

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

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

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

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

## 17. Grading of performances

### 17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 30.

Table–30: Letter grades and grade points equivalent to Percentage of marks and performances.

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

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

## 18. The Semester grade point average (SGPA)

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

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO}{C_1 + C_2 + C_3 + C_4}$$

## 19. Cumulative Grade Point Average (CGPA)

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

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where $C_1$, $C_2$, $C_3$,.... is the total number of credits for semester I,II,III,.... and $S_1$,$S_2$, $S_3$,...is the SGPA of semester I,II,III,..... .

## 20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

## 21. Project work

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

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

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

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

## 22. Award of Ranks

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

## 23. Award of degree

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

## 24. Duration for completion of the program of study

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

## 25. Revaluation I Retotaling of answer papers

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

## 26. Re-admission after break of study

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

# PHARMACEUTICAL ANALYSIS (MPA)

## SEMESTER - I

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
## (MPA 101T)

### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

### Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. — 10 Hrs

   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 (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. — 10 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. — 10 Hrs

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

| | | |
|---|---|---|
| | a. Thin Layer chromatography<br>b. High Performance Thin Layer Chromatography<br>c. Ion exchange chromatography<br>d. Column chromatography<br>e. Gas chromatography<br>f. High Performance Liquid chromatography<br>g. Ultra High Performance Liquidchromatography<br>h. Affinity chromatography<br>i. Gel Chromatography | 10 Hrs |
| 5 | a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>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 | 10 Hrs |
| 6 | Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.<br>Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. | 10 Hrs |

REFERENCES


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

# ADVANCED PHARMACEUTICAL ANALYSIS
## (MPA 102T)

### Scope

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

### Objective

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY — 60 Hrs

1. **Impurity and stability studies:** — 10 Hrs

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

**Impurities in new drug products:**

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

**Impurities in residual solvents:**

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

2 **Elemental impurities:** — 10 Hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

**Stability testing protocols:**

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

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| 3 | Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products | 10 Hrs |
| 4 | **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. | 10 Hrs |
| 5 | **Biological tests and assays of the following:** a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures) | 10 Hrs |
| 6 | Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. | 10 Hrs |

REFERENCES


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

# PHARMACEUTICAL VALIDATION
## (MPA 103T)

### Scope

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

### Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY — 60 Hrs

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| 1. | Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.<br>Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments. | 12 Hrs |
| 2 | Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette. | 12 Hrs |
| 3 | Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). | 12 Hrs |
| 4 | Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.<br>Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5. | 12 Hrs |

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| 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 applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. | 12 Hrs |

REFERENCES


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

# FOOD ANALYSIS
## (MPA 104T)

### Scope

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

### Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY 60 Hrs

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 fibre, Crude fibre and application of food carbohydrates
   Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins. — 12 Hrs

2 Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.
Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series. — 12 Hrs

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 Hrs

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| 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.<br>Analysis of fermentation products like wine, spirits, beer and vinegar. | 12 Hrs |
| 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.<br>Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. | 12 Hrs |

REFERENCES


1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

## PHARMACEUTICAL ANALYSIS PRACTICAL - I
## (MPA 105PA)

1. Calibration of glasswares
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. Imupurity profiling of drugs
9. Assay of official compounds by different titrations
10. Assay of official compounds by instrumental techniques.
11. Estimation of riboflavin/quinine sulphate by fluorimetry
12. Estimation of sodium/potassium by flame photometry
13. Quantitative determination of hydroxyl group.
14. Quantitative determination of amino group
15. Colorimetric determination of drugs by using different reagents

## PHARMACEUTICAL ANALYSIS PRACTICAL - II
## (MPA 105PB)

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. Determination of total reducing sugar
6. Determination of proteins
7. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
8. Determination of fat content and rancidity in food products
9. Analysis of natural and synthetic colors in food
10. Determination of preservatives in food
11. Determination of pesticide residue in food products
12. Analysis of vitamin content in food products
13. Determination of density and specific gravity of foods
14. Determination of food additives

SEMESTER - II

# ADVANCED INSTRUMENTAL ANALYSIS

(MPA 201T)

## Scope

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

## Objectives

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

| THEORY | | 60 Hrs |
|---|---|---|
| 1. | HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. | 12 Hrs |
| 2 | Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.<br>Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications. | 12 Hrs |
| 3 | Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.<br>Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation | 12 Hrs |

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| 4 | Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. | 12 Hrs |
| 5 | NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. | 12 Hrs |

REFERENCES


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

# MODERN BIO-ANALYTICAL TECHNIQUES
## (MPA 202T)

### Scope

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

### Objectives

Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY 60 Hrs

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. 12 Hrs

   Bioanalytical method validation: USFDA and EMEA guidelines.

2 **Biopharmaceutical Consideration:**

Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. 12 Hrs

3 **Pharmacokinetics and Toxicokinetics:**

Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics. 12 Hrs

4 **Cell culture techniques**

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

5 **Metabolite identification:** 12 Hrs

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met–ID. Regulatory perspectives.

In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES


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

# QUALITY CONTROL AND QUALITY ASSURANCE
## (MPA 203T)

### Scope

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

### Objectives

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

THEORY — 60 hrs

1. **Concept and Evolution of Quality Control and Quality Assurance** — 12 Hrs

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

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. — 12 Hrs

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) — 12 Hrs

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

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. 12 Hrs

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 Hrs

REFERENCES


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

# HERBAL AND COSMETIC ANALYSIS

## (MPA 204T)

### Scope

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

### Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY 60 Hrs

1. Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines. — 12 Hrs

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 Hrs

**Regulatory requirements for setting herbal drug industry:**

Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3 Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. — 12 Hrs

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic

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

| | | |
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| 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 Hrs |
| 5 | Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.<br>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 Hrs |

REFERENCES


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

## PHARMACEUTICAL ANALYSIS PRACTICAL - III
## (MPA 205PA)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical / Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.

## PHARMACEUTICAL ANALYSIS PRACTICAL - IV
## (MPA 205PB)

1. In process and finished product quality control tests for tablets, capsules, parenterals and creams
2. Quality control tests for Primary and secondary packing materials
3. Assay of raw materials as per official monographs
4. Testing of related and foreign substances in drugs and raw materials
5. Preparation of Master Formula Record.
6. Preparation of Batch Manufacturing Record.
7. Quantitative analysis of rancidity in lipsticks and hair oil
8. Determination of aryl amine content and Developer in hair dye
9. Determination of foam height and SLS content of Shampoo.
10. Determination of total fatty matter in creams (Soap, skin and hair creams)
11. Determination of acid value and saponification value.
12. Determination of calcium thioglycolate in depilatories

# Semester III

## MRM 301T - Research Methodology & Biostatistics

UNIT – I

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.

UNIT – II

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

UNIT – III

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.

UNIT – IV

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.

UNIT – V

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