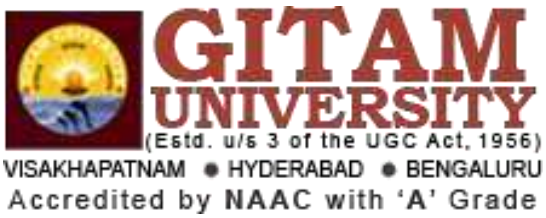
GANDHI INSTITUTE OF TECHNOLOGY AND MANAGEMENT
(GITAM)
(Deemed to be University, Estd. u/s 3 of the UGC Act 1956)
*VISAKHAPATNAM * HYDERABAD *BENGALURU*
Accredited by NAAC with 'A' Grade



REGULATIONS & SYLLABUS

MASTER OF PHARMACY
(M. Pharm. Pharmaceutical Analysis)
(W.e.f. 2017- 18 admitted batch)

Website: **www.gitam.edu**

MASTER OF PHARMACY (M. Pharm. Pharmaceutical Analysis)
REGULATIONS as per PCI
(w.e.f. 2017-2018 admitted batch)

1.0 ADMISSIONS

1.1 Admissions into M. Pharmacy programme of GITAM University are governed by GITAM University admission regulations.

2.0 MINIMUM QUALIFICATION FOR ADMISSION

A Pass in the following examinations

2.1 B. Pharm. Degree examination of an Indian University established by law in India from an institution approved by Pharmacy Council of India (PCI) and has scored not less than 50 % of the maximum marks (aggregate of 4 years of B. Pharm.)

2.2 Every student, selected for admission to post graduate pharmacy programme 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.

2.3 Admissions into M. Pharm. will be based on All India Entrance Test (GAT - PGP) conducted by GITAM University and the rule of reservation is followed wherever applicable.

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 PROGRAMME

The programme of study for M. Pharm. shall extend over a period of four semesters (two academic years).

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 November/December to April/May 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. PROGRAMME/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/extracurricular 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.** These credits are divided into theory courses, practical, seminars, assignments, research work, discussions with the supervisor and journal club over the duration of four semesters. The credits are distributed semester-wise as shown in Table 8. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. ACADEMIC WORK

A regular record of attendance both in theory, practical, seminar, assignment, journal club, discussion with the supervisor, research work presentation and dissertation shall be maintained by the department / teaching staff of respective courses.

9. COURSE OF STUDY

The course of study for M. Pharm. specialization shall include semester wise theory & practical as given in Table –1 to 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table –1 to 3.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA 102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA 103T	Pharmaceutical Validation	4	4	4	100
MPA 104T	Food Analysis	4	4	4	100
MPA 105P	Pharmaceutical Analysis Practical – I	12	6	12	150
MPA 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPA 201T	Advanced Instrumental Analysis	4	4	4	100
MPA 202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA 203T	Quality Control and Quality Assurance	4	4	4	100
MPA 204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA 205P	Pharmaceutical Analysis Practical – II	12	6	12	150
MPA 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit points
MRM 301T	Research Methodology and Biostatistics*****	4	4
MPR 301T	Journal club	2	2
MPR 302T	Discussion/Presentation (Proposal presentation)	2	2
MPR 303P	Research Work	28	14

	(Proposed project work, Literature survey, Plan of work, Methodology)		
Total		36	22

* Non University Exam

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

Course Code	Course	Credit Hours	Credit points
MPR 401T	Discussion/ Final Presentation (Presentation of work, communication skills, question and answers)	3	3
MPR 402P	Research work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	36	18
Total		39	21

Table – 4: Semester wise credits distribution

Semester	Credit points
I	26
II	26
III	22
IV	21
Total Credit Points	**95**

10. PROGRAMME COMMITTEE

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

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

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.

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

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

iv. Communicating its recommendation to the Head of the institution on academic matters.

v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. EXAMINATIONS/ASSESSMENTS

The schemes for internal assessment and end semester examinations are given in Table –5 to 6.

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 (*) in table 6 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.

Table – 11: Schemes for internal assessments and end semester (Pharmaceutical Analysis – MPA)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPA 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPA 102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hr	100
MPA 104T	Food Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 105P	Pharmaceutical Analysis Practical – I	20	30	6 Hr	50	100	6 Hr	150
MPA 106P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650
Semester II								
MPA 201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPA 203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hr	100
MPA 204T	Herbal and Cosmetic Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 205P	Pharmaceutical Analysis Practical – II	20	30	6 Hr	50	100	6 Hr	150
MPA 206P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650

Table – 6: Schemes for internal assessments and end semester examinations

(Semester III & IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hr	100
MPR 301T	Journal club	-	-	-	100	-	-	100
MPR 302T	Discussion/Presentation (Proposal presentation)	-	-	-	100	-	-	100
MPR 303P	Research Work (proposed project work, Literature survey, Plan of work, Methodology)	-	-	-	-	100	1 Hr	100
Total								400
Semester IV								
MPR 401T	Discussion/ Presentation (Presentation of work, communication skills, question and answers)	-	-	-	100	-	-	100
MPR 402P	Research Work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	-	-	-	-	100	1 Hr	100
Total								200

* Non University Examination

11.2. **Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as follows.

Table – 7: Scheme for awarding internal assessment: Continuous mode

Criteria	Maximum Marks
Theory	
Attendance (Refer Table -5)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 5)	10
Based on Practical Records, Regular viva voce, etc.	10

Total	20

Table – 8: Guidelines for 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 **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 tables 5 – 6. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. PROMOTION AND AWARD OF GRADES

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

13. CARRY FORWARD OF MARKS

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

14. IMPROVEMENT OF INTERNAL ASSESSMENT

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

15. REEXAMINATION OF END SEMESTER EXAMINATIONS

Reexamination of end semester examination shall be conducted as per the schedule given in table 9. The exact dates of examinations shall be notified from time to time.

Table – 9: Tentative schedule of end semester examinations

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

16. ALLOWED TO KEEP TERMS (ATKT):

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

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed. A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

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

17. GRADING OF PERFORMANCES

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 10.

Table – 10: 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:

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

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

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

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:

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

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

20. DECLARATION OF CLASS

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

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

21. PROJECT WORK

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

The internal and external examiner appointed by the University shall evaluate the project at the time of the practical examinations of other semester(s).

22. AWARD OF RANKS

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M. Pharm. programme shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm. programme 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 PROGRAMME OF STUDY

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

25. REVALUATION/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 programme after break of study has to get the approval from the University by paying a condonation fee.

27. PROGRAM OUTCOMES (PO)

PO1: A detailed understanding of various Instrumental techniques available for the Pharmaceutical analysis used in the quality control of APIs and Pharmaceutical dosage forms in pharmaceutical industries.

PO2: To understand and apply the instrumental techniques for the identification of the purity, assay, residual solvents, stability studies.

PO3: To understand the validation of different analytical methods and to understand the acceptable criteria as per the ICH guidelines.

PO4: A detailed knowledge about the Impurity profiling of various pharmaceuticals during the storage, manufacturing process and the process related reactions and their involvement.

PO5: Interpretation and identification of the root cause for the occurrence of the impurities by the possible and plausible pathways and thereby confirmation for further bio analytical studies.

28. PROGRAM SPECIFIC OUTCOMES (PSO)

PSO1: To deal with various Advanced Instrumental Techniques as well as Hyphenated Analytical Instrumental Techniques for the identification, characterization, and quantification of drug molecules (Active Pharmaceutical Ingredient) and drug products.

PSO2: To know the science of detection of impurities, impurities in pharmaceutical formulations, impurity profiling, stability testing of phytopharmceuticals, and their protocol development.

PSO3: To understand validation and its application in industry, their methodologies and application in manufacturing processes.

PSO4: To impart knowledge on analysis of food constituents and finished food products, food additives, the pesticides and the regulations of food and legislations of food products.

PSO5: To know the Pharmacopoeia assays by spectroscopical methods, calibration techniques, determination of preservatives, vitamin contents in drugs and foods

PSO6: To impart knowledge about extraction, separation of drugs from biological samples using different techniques and guidelines for analytical methods

PSO7: To know about quality assurance aspects of pharmaceutical industries such as CGMP, Documentations, certifications, GLP, and other regulatory affairs

PSO8: To create a talent pool by involving students in research projects and to make students undertake research projects under faculty guidance for publication.

SEMESTER – I

PHARMACEUTICAL ANALYSIS (MPA)

MPA 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to provide the student with basic information about various instrumental techniques covering spectroscopy, chromatography and thermal analysis. During the course the student will be learning the concepts and applications of various absorption (UV-Visible, IR) and emission (Spectrofluorimetry, Flame photometry) spectroscopic techniques along with X-ray crystallography, NMR and Mass spectroscopy. The student will also gain knowledge on the significance of various basic to complex chromatographic (TLC, HPLC, GC, Affinity chromatography) and electrophoresis (Gel, Moving boundary) techniques.

Course objectives: 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.

UNIT – I **12 Hrs**

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.
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.

UNIT – II **12 Hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, principle, instrumentation, solvent requirement in NMR, relaxation process, NMR signals in various compounds, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, nuclear magnetic double resonance, brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

UNIT – III **12 Hrs**

Mass Spectroscopy: Principle, theory, instrumentation of mass spectroscopy, different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers of quadrupole and time of flight, mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectroscopy.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of gel electrophoresis and moving boundary electrophoresis

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:

Differential Scanning Calorimetry (DSC): 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).

Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Course Outcomes: After completion of course student is able to know,

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

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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 – A H Beckett and J B 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 edition, P.S/Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K A Connors, 3rd edition, John Wiley & Sons, 1982.

MPA 102T. ADVANCED PHARMACEUTICAL ANALYSIS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to provide the student with basic information about the regulatory requirements of stability testing and impurity study in pharmaceuticals. The students will be given a deep insight into the impurity profiling and degradant characterization as per the WHO and ICH guidelines. Special emphasis will be given to the stability testing of phytopharmaceuticals and biological tests and PCR studies.

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

UNIT – I **12 Hrs**

Impurity and stability studies:
Definition, classification of impurities in drug Substance or active pharmaceutical ingredients and quantification of impurities as per ICH guidelines
Impurities in new drug products:
Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
Impurities in residual solvents:
General principles, classification of residual solvents, analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT – II **12 Hrs**

Elemental impurities:
Element classification, control of elemental impurities, potential sources of elemental impurities, identification of potential elemental impurities, analytical procedures, instrumentation & C, H, N and S analysis
Stability testing protocols:
Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations.

UNIT – III **12 Hrs**

Impurity profiling and degradant characterization: Method development, stability studies and concepts of validation, accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products.

UNIT – IV **12 Hrs**

a. Stability testing of phytopharmaceuticals:
Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.
b. Immunoassays (IA) Basic principles, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, quantification and applications of IA.

UNIT –V **12 Hrs**

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)

Course Outcomes: 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.

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 Garratt, 3rd edition, CBS Publishers, New Delhi, 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.

MPA 103T. PHARMACEUTICAL VALIDATION

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to provide the student with basic information about the concepts and significance of qualification and calibration with detailed description of procedures for various analytical instruments and glassware. The importance of validation, types of validation as per ICH, USFDA and USP will be discussed in a detailed manner to enlighten the student on the present need of the industry. Special emphasis will be given on the concepts of IPR.

Course objectives: 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.

UNIT – I **12 Hrs**

Introduction: Definition of qualification and validation, advantage of validation, streamlining of qualification & validation process and validation master plan.

Qualification: User requirement specification, design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), installation qualification, operational qualification, performance qualification, re-qualification (maintaining status calibration preventive maintenance, change management), qualification of manufacturing equipments, qualification of analytical instruments and laboratory equipments.

UNIT – II **12 Hrs**

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT – III **12 Hrs**

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, compressed air and nitrogen.

Cleaning Validation: Cleaning method development, validation of analytical method used in cleaning. Cleaning of equipment, cleaning of facilities. Cleaning in place (CIP).

UNIT – IV **12 Hrs**

Analytical method validation: General principles, validation of analytical method as per ICH guidelines and USP.

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

UNIT – V **12 Hrs**

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of intellectual property –patents, copyright, trademark; factors affecting choice of IP protection; penalties for violation; role of IP in pharmaceutical

industry; global ramification and financial implications. Filing patent applications; 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 technology (TOT), IP and ethics-positive and negative aspects of IPP; societal responsibility, avoiding unethical practices.

Course Outcomes: 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

References

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd edition., 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 edition., Marcel Dekker Inc., N.Y.
6. Validation of 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 edition.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

MPA 104T. FOOD ANALYSIS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This course deals with basic information about various food constituents like carbohydrates, proteins, lipids and vitamins along with analytical methods designed for their analysis. The course also covers information on analytical methods for food additives, milk and fermentation products. Special emphasis is given to pesticide analysis and legislation regulations (BIS, AGMARK) on food products.

Course objectives: 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

UNIT – I **12 Hrs**

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.

UNIT – II **12 Hrs**

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.

UNIT – III **12 Hrs**

Food additives: Introduction, analysis of preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, non-permitted synthetic dyes used by industries, method of detection of natural, permitted and non-permitted dyes.

UNIT – IV **12 Hrs**

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.

UNIT – V **12 Hrs**

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.

Course Outcomes: 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

References

1. The chemical analysis of foods – David Pearson, 7th 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, 6th edition, Vol. 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.

MPA 105P. PHARMACEUTICAL ANALYSIS PRACTICALS – I

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

SEMESTER – II

MPA 201T. ADVANCED INSTRUMENTAL ANALYSIS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to give information on the recent advances in instrumental techniques like HPLC, GC, SFC, Mass and NMR. The student will have an insight into the spectral interpretations leading to the applications of the techniques. Different hyphenated techniques and their significance will be delivered to the students. Special emphasis will also be given to the students on chiral analysis and HILIC approaches.

Course objectives: 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.

UNIT – I **12 Hrs**

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

UNIT – II **12 Hrs**

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.
High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

UNIT – III **12 Hrs**

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.
Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

UNIT – IV **12 Hrs**

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALDI, 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 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.

UNIT – V **12 Hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, principle, instrumentation, solvent requirement in NMR, relaxation process, NMR signals in various compounds, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, nuclear magnetic double resonance, brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, interpretation and applications of NMR spectroscopy. LC-NMR hyphenations.

Course Outcomes: : 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

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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 II, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th edition.

MPA 202T. MODERN BIO-ANALYTICAL TECHNIQUES

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This course deals with various aspects of analysis of pharmaceuticals in biological matrices. The students are taught about different extraction techniques for drugs and metabolites, biopharmaceutical considerations, pharmocokinetic and toxicokinetic evaluations along with metabolite identification in different biological matrices. The students will also be introduced to cell culture techniques and cell viability assays.

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

UNIT – I **12 Hrs**

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the bioanalytical methods such as protein precipitation, liquid liquid

extraction and solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines.

UNIT – II **12 Hrs**

Biopharmaceutical consideration: Introduction, biopharmaceutical factors affecting drug bioavailability, In Vitro dissolution and drug release testing, alternative methods of dissolution testing transport models, biopharmaceutics classification system. Solubility: Experimental methods. Permeability: In-vitro, in-situ and in-vivo methods.

UNIT – III **12 Hrs**

Pharmacokinetics and Toxicokinetics: Basic consideration, drug interaction (PK-PD interactions), the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome P450-based drug interactions, drug interactions linked to transporters. Microsomal assays

Toxicokinetics - Toxicokinetic evaluation in preclinical studies, importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met – ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. Drug product performance, in vivo bioavailability and bioequivalence: Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, generic biologics (biosimilar drug products), clinical significance of bioequivalence studies.

Course Outcomes: : 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.

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

MPA 203T QUALITY CONTROL AND QUALITY ASSURANCE

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This course is designed to enlighten the students with the present concepts quality control and quality assurance in pharma industry. A detailed discussion will be given on ICH, GLP, GMP (Schedule M, USFDA, WHO). The students are also trained on the quality control tests of raw materials and dosage forms as per IP, BP and USP. Special emphasis will be given on the documentation practices, manufacturing operations and controls regularly implemented in the industry.

Course objectives: 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.

UNIT – I **12 Hrs**

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

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, quality control test for containers, closures and secondary packing materials.

UNIT – IV **12 Hrs**

Documentation in pharmaceutical industry: Three tier documentation, policy, procedures and work instructions, and records (formats), basic principles- how to maintain, retention and retrieval etc. Standard operating procedures, master formula record, batch formula record, quality audit plan and reports. Specification and test procedures, protocols and reports. Distribution records. Electronic data.

UNIT – V **12 Hrs**

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

Course Outcomes: 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

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 compendium 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, Excipients 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, 6th edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

MPA 204T. HERBAL AND COSMETIC ANALYSIS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to educate the students on the concepts of herbal analysis. A deep insight will be given into the herbal drug standardization as per WHO and AYUSH, aspects of adulteration and deterioration, DNA fingerprinting and patent law. Special emphasis will be given to the testing of natural products and drugs with reference to the monographs from Pharmacopoeias, herbal drug-drug interactions and evaluation of herbal cosmetics as per BIS.

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

UNIT – I **12 Hrs**

Herbal remedies- Toxicity and Regulations: Herbals vs conventional drugs, efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamic and pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

UNIT – II **12 Hrs**

Adulteration and deterioration: Introduction, types of adulteration/substitution of herbal drugs, causes and measure of adulteration, sampling procedures, determination of foreign matter, and DNA finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable to herbal drugs and natural products and its protocol.

UNIT – III **12 Hrs**

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, regulation and dispensing of herbal drugs, stability testing of natural products, protocol. Monographs of herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, Siddha and Unani pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT – IV **12 Hrs**

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.

UNIT – V **12 Hrs**

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals,

fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

Course outcome: 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.

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, 7th edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th edition, Poucher's Perfumes, Cosmetics and Soaps, Kluwer Academic Publishers.
13. A O Barel, M Paye, H I Maibach, Handbook of Cosmetic Science and Technology, 3rd edition, CRC Press, 2009.

MPA 205P. PHARMACEUTICAL ANALYSIS PRACTICALS – II

Hours per week: 12 — End Examination: 100 Marks
Credit: 6 — Midsem: 50 Marks

1. Comparison of absorption spectra by UV and Wood ward – Fieser 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.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

SEMESTER – III

MRM 301T. RESEARCH METHODOLOGY & BIOSTATISTICS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This introductory course of research methodologies and biostatistics will give students an overview of the many study designs and statistical tests that are used in the medical industry to answer research issues. This course focuses on the CPCSEA guidelines and prerequisites for performing animal experiments, categorising research projects, developing a study, experimental design, measuring and interpreting data, and conducting ethical research.

Course objectives: Impart knowledge on statistical principles that can be applied to design experiments and help in the interpretation of the results.

UNIT – I **12 Hrs**

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 **12 Hrs**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts.
Measures of central tendency: Computation of means, median and mode from grouped and ungrouped data. Measure of dispersion: Computation of variance, standard deviation, standard error and their coefficients.

UNIT – III **12 Hrs**

Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.
Probability rules: Binomial, poison and normal distribution.

UNIT – IV **12 Hrs**

Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi-square tests in pharmaceutical and medical research. Analysis of Variance: 1-way, 2-way and 3-way classification. Non-parametric tests: Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

UNIT – V **12 Hrs**

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.

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

Course Outcomes: Upon completion of the course the student is able to select appropriate statistical methods required for a particular research design and develop appropriate research hypothesis for a research project. Develop appropriate framework for research studies. Gain knowledge regarding CPCSEA guidelines and prerequisites for conducting animal experiments.

References

1. Santosh Gupta: "Research Methodology and Statistical Techniques", Deep & Deep Publication, 2001

2. C. R. Kothari: "Research Methodology – Methods & Techniques", 2nd edition, Wishwa Prakashan, 2000.

3. K. P. C. Swain:"A Text book of Research Methodology", 1st edition, Kalyani Publishers, 2007.

4. "Research Methodology and Statistical Techniques" Indira Gandhi National Open University.

5. M. N. Ghosh: "Fundamentals of Experimental Pharmacology", 2nd edition, Scientific Book Agency, Calcutta, India, 1984.

6. H. G. Vogel: "Drug Discovery and Evaluation-Pharmacological Assays", 2nd edition, Springer Verlag, Berlin, Germany, 2002.