Scheme and Syllabus

M. Pharmacy
Pharmaceutical Analysis

Batch 2017 onwards

PTU

ਆਈ. ਕੇ. ਗੁਜਰਾਲ ਪੰਜਾਬ ਟੈਕਨੀਕਲ ਯੂਨੀਵਰਸਿਟੀ

By
Board of Studies Pharmacy
Department of Academics

First Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPA101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	100	4
MPA102T	Advanced Pharmaceutical Analysis	4	-	25	75	100	4
MPA103T	Pharmaceutical Validation	4	-	25	75	100	4
MPA104T	Food Analysis	4		25	75	100	4
MPA105P	Pharmaceutical Analysis Practical I	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Second Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPA201T	Advanced Instrumental Analysis	4	-	25	75	100	4
MPA202T	Modern Bio-Analytical Techniques	4	-	25	75	100	4
MPA203T	Quality Control & Quality Assurance	4	-	25	75	100	4
MPA204T	Herbal & Cosmetic Analysis	4		25	75	100	4
MPA205P	Pharmaceutical Analysis Practical II	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Third Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	**External**	**Total**	
MRM301T	Research Methodology & Biostatistics*	4	-	25	75	100	4
-	Journal Club	1	-	25	-	25	1
-	Discussion / Presentation (Proposal Presentation)	2	-	50	-	50	2
-	Research Work*	-	28	-	350	350	14
	Total	**7**	**28**	**100**	**425**	**525**	**21**

- *Non -University Exam

Fourth Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
-	Journal Club	1	-	25	-	25	1
-	Research Work	-	31	-	400	400	16
-	Discussion/Final Presentation	3	-	75	-	75	3
-	Co-curricular Activities	-	-	Satisfactory/Unsatisfactory			2*
Total		**4**	**31**	**100**	**400**	**500**	**22**

**Note: Required credit points 02 for satisfactory; Less than 02 credit points unsatisfactory*

***Credits not included towards calculation of CGPA**

Semester Wise Credits Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations & Other Scholarly Activities)	02*
Total Credit Points	**93 + 2* = 95**

- *Credit Points for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- *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

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) OR Academic Award/Research Award from State Level/National Agencies	02
Participation in International Level Seminar/ Conference/ Workshop/ Symposium / Training Programs (related to the specialization of the student) #	02
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

- #International Conference held even in India will be considered for award of Credit Points.
- *Only those research / review publications will be considered which have been published during the tenure of M. Pharm. Course.
- $ International Journal: The Editorial Board outside India.

Academic Work

The department / teaching staff of respective courses shall maintain a regular record of attendance in Theory, Practical, Seminar, Assignment, Journal Club, and Discussion with the supervisor, Research work presentation and Dissertation.

Program Committee

1. 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. A teacher at the cadre of Professor shall be the Chairperson
   b. One Teacher from each M. Pharm. Specialization
   c. Four student representatives (two from each academic year), nominated by the Head of the Institution
3. Duties of the Programme Committee:
   a. Periodically review the progress of the classes.
   b. Discuss the problems concerning curriculum, syllabus and the conduct of classes.
   c. 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.

Sessional Exams

- Two sessional exams shall be conducted for each theory/practical course
- The average marks of two sessional exams shall be computed for internal assessment
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 15 marks**.
- Sessional exam for practical shall be **conducted for 40 marks** and shall be **computed for 30 marks**.

Question Paper Pattern for Theory Sessional Examinations

Multiple Choice Questions (MCQs) **OR** Objective Type Questions (5 x 2) (Answer all the questions)	10 x 1 = 10 **OR** 05 x 2 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Total	**30 Marks**

Question Paper Pattern for Practical Sessional Examinations

Synopsis	10
Experiments	25
Viva voce	05
Total	**40 Marks**

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. Theory Courses having Internal of 25 Marks the scheme of internal award is:
    - Sessional Exams: 15 Marks
    - Continuous Mode: 10 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	08
Student – Teacher interaction	02
Total	**10**

2. Practical Courses having Internal of 50 Marks the scheme of internal award is:
    - Sessional Exams: 30 Marks
    - Continuous Mode: 20 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

***Guidelines for the Allotment of Marks for Attendance**

Percentage of Attendance	Theory (Maximum Marks 08)	Practical (Maximum Marks 10)
95 – 100	08	10
90 – 94	06	7.5
85 – 89	04	5
80 – 84	02	2.5
Less than 80	0	0

1st SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	1	3	4

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

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments.

Module 01 **10 Hour**

UV-Visible Spectroscopy

- Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy
- Choice of solvents and solvent effect
- Applications of UV- Visible spectroscopy, Difference/ Derivative spectroscopy

IR Spectroscopy

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

Spectroflourimetry

- Theory of Fluorescence
- Factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation
- Applications of fluorescence spectrophotometer

Flame Emission Spectroscopy and Atomic Absorption Spectroscopy

- Principle, Instrumentation, Interferences and Applications

Module 02 **10 Hours**

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 ^{13}C NMR
- Applications of NMR spectroscopy

Module 03 **10 Hours**

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
- Applications of Mass spectroscopy

Module 04 **10Hours**

Chromatography

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

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

Module 05 **10Hours**

Electrophoresis

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Isoelectric focusing

X ray Crystallography

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

Module 06 **10 Hours**

Potentiometry

- Principle, working, ion selective electrodes
- Application of potentiometry

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
- Advantage and disadvantages
- Pharmaceutical applications
- Derivative differential thermal analysis (DDTA)

TGA

- Principle, instrumentation
- Factors affecting results
- Advantage and disadvantages
- Pharmaceutical applications

Recommended Books (Latest editions)

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

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA102T	Advanced Pharmaceutical Analysis	4	-	25	75	1	3	4

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.

Objectives: After completion of the course students shall able to know

1. Appropriate analytical skills required for the analytical method development.
2. 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.
3. Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products.

Module 01 **10Hours**

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

Module 02 **10Hours**

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

Module 03 **10Hours**

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

Module 04 **10 Hours**

Stability testing of Phytopharmaceuticals

- Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity

Module 05 **10Hours**

Biological Tests and Assays of The Following

- Adsorbed Tetanus vaccine
- Adsorbed Diphtheria vaccine
- Human anti haemophilic vaccine
- Rabies vaccine
- Tetanus Anti toxin
- Tetanus Anti serum
- Oxytocin
- Heparin sodium IP
- Antivenom

PCR

- PCR studies for gene regulation, instrumentation (Principle and Procedures)

Module 06 **10 Hours**

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

Recommended Books (Latest editions)

1. Vogel‘s textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, ELBS.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, CBS publishers, New Delhi.
3. Textbook of Pharmaceutical Analysis - K A Connors, John Wiley & Sons.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, Wiley – Inter science Publication.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, CBS Publishers New Delhi.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, CBS Publishers, New Delhi.
8. Indian Pharmacopoeia Vol I, II & III.
9. Methods of sampling and microbiological examination of water, BIS.
10. Practical HPLC method development – Snyder, Kirkland, Glajch, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier.
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA103T	Pharmaceutical Validation	4	-	25	75	1	3	4

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 course, student shall be able to

1. Explain the aspect of validation.
2. Explain the aspect of validation.
3. Apply the knowledge of validation to instruments and equipments.
4. Validate the manufacturing facilities.

Module 01 **12 Hours**

Introduction

- Definition of Qualification and Validation
- Advantage of Validation
- Streamlining of Qualification & Validation process
- 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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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)

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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 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

Recommended Books (Latest editions)

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation, Drugs and Pharm Sci. Series, Vol. 129, Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 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, by Carleton & Agalloco, Marcel Dekker.
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 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.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA104T	Food Analysis	4	-	25	75	1	3	4

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

1. Food constituents.
2. Food additives.
3. Finished food products.
4. Pesticides in food.
5. Student shall have the knowledge on food regulations and legislations.

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

- 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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

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

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA105P	Pharmaceutical Analysis Practical - I	-	12	50	100	6	6	6

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. Imupurity 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

2nd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA201T	Advanced Instrumental Analysis	4	-	25	75	1	3	4

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

1. Interpretation of the NMR, Mass and IR spectra of various organic compounds.
2. Theoretical and practical skills of the hyphenated instruments.
3. Identification of organic compounds.

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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 ^{13}CNMR, Spin spin and spin lattice relaxation phenomenon
- ^{13}CNMR, 1-D and 2-D NMR, NOESY and COSY techniques
- Interpretation and Applications of NMR spectroscopy
- LC-NMR hyphenations

Recommended Books (Latest editions)

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, CBS publishers.
4. Organic Spectroscopy - William Kemp, ELBS.
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, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA202T	Modern Bio-Analytical Techniques	4	-	25	75	1	3	4

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

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

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

1. Analysis of drugs in Biological fluids - Joseph Chamberlain. CRC Press, New York.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, Eastern press, Bangalore.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, Wiley – Interscience Publications.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series,
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, Marcel Dekker, New York, USA.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA.

8. Good Laboratory Practice Regulations, Sandy Weinberg Vol. 69, Marcel Dekker Series.
9. Good Laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series.
10. ICH, USFDA & CDSCO Guidelines.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA203T	Quality Control & Quality Assurance	4	-	25	75	1	3	4

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

1. The cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments

Module 01 **12 Hours**

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

Module 02 **12 Hours**

Computational Modeling of Drug Disposition

- 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 layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination
- Good Warehousing Practice
- CPCSEA guidelines

Module 03 **12 Hours**

- Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC)
- Developing specification (ICH Q6 and Q3)
- Purchase specifications and maintenance of stores for raw materials
- In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules,

ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials

Module 04 **12 Hours**

Documentation in Pharmaceutical Industry

- Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention 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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, Volume I & II, Mumbai.
2. Good Laboratory Practice Regulations, Sandy Weinberg Vol. 69, Marcel Dekker Series.
3. Quality Assurance of Pharmaceuticals- A compedium of Guidelines and Related materials Vol I & II, WHO Publications.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, WHO, Geneva.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, Susmit Publishers.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 1 - With Checklists and Software Package), Taylor & Francis.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals, John Wiley & Sons.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA204T	Herbal & Cosmetic Analysis	4	-	25	75	1	3	4

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

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

Module 01 **12 Hours**

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

Module 02 **12 Hours**

Adulteration and Deterioration

- Introduction, types of adulteration/substitution of herbal drugs
- Causes and Measure of adulteration
- Sampling Procedures
- Determination of Foreign Matter
- DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations

Regulatory Requirements for Setting Herbal Drug Industry

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

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, 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.
10. Suppliers catalogue on specialized cosmetic excipients.
11. Wilkinson, Moore, George Godwin, Poucher's Perfumes, Cosmetics and Soaps.
12. Hilda Butler, Kluwer Handbook of Cosmetic Science and Technology, Academic Publishers.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPA205P	Pharmaceutical Analysis Practical - II	-	12	50	100	6	6	6

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
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

3rd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MRM301T	Research Methodology & Biostatistics	4	-	25	75	1	3	4

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

Declaration of Helsinki

- History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care

Recommended Books (Latest editions)

1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
3. Methods in Biostatistics, B.K. Mahajan. JAYPEE Brothers Medical Publishers (P) Ltd.
4. CPCSEA Guidelines.
   A Handbook of Applied Statistics in Pharmacology, Katsumi Kobayashi and K. Sadasivan Pillai. CRC Press, Taylor & Francis Group.