

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650



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

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

\* Non University Exam

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

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

**Table – 14: Semester wise credits distribution**

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

\*Credit Points for Co-curricular Activities

## ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

### Scope

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

### Objectives

After completion of course student is able to know,  
interpretation of the NMR, Mass and IR spectra of various organic compounds  
theoretical and practical skills of the hyphenated instruments identification of organic compounds

### THEORY

60 Hrs

1. HPLC: Principle, instrumentation, pharmaceutical applications, 12 peak shapes, capacity factor, selectivity, plate number, plate Hrs 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.
2. Biochromatography: Size exclusion chromatography, ion 12 exchange chromatography, ion pair chromatography, affinity Hrs 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.
3. Super critical fluid chromatography: 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.

- 4 Mass spectrometry: Principle, theory, instrumentation of mass 12 spectrometry, different types of ionization like electron impact, Hrs 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.

- 5 NMR spectroscopy: Quantum numbers and their role in NMR, 12 Hrs 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 <sup>13</sup>C NMR: Spin spin and spin lattice relaxation phenomenon. <sup>13</sup>C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

#### REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7<sup>th</sup> edition, CBS publishers.
4. Organic Spectroscopy – William Kemp, 3<sup>rd</sup> 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, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis– Modern methods – Part B – J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

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

### Scope

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

### Objectives

Upon completion of the course, the student shall be able to understand  
Extraction of drugs from biological samples  
Separation of drugs from biological samples using different techniques  
Guidelines for BA/BE studies.

### THEORY

60 Hrs

1. Extraction of drugs and metabolites from biological matrices: 12 General  
need, principle and procedure involved in the Hrs  
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.
2. Biopharmaceutical Consideration: 12  
Introduction, Biopharmaceutical Factors Affecting Drug Hrs  
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.  
(Approved by AICTE, PCI and Affiliated to Osmania University)
3. Pharmacokinetics and Toxicokinetics: 12  
Basic consideration, Drug interaction (PK–PD interactions), The Hrs  
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.
4. Cell culture techniques 12  
Basic equipments used in cell culture lab. Cell culture media, Hrs  
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.

- 5 Metabolite identification: 12 Hrs  
In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

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

#### REFERENCES

1. Analysis of drugs in Biological fluids – Joseph Chamberlain, 2<sup>nd</sup> Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis – Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis – Higuchi, Brochmman and Hassen, 2<sup>nd</sup> 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, 2<sup>nd</sup> Edition, John Wiley & Sons, New Jerco. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2<sup>nd</sup> Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jerco, USA. 2007.
8. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

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

### Scope

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

### Objectives

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

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

to understand the responsibilities of QA & QC departments

### THEORY

60 hrs

1. Concept and Evolution of Quality Control and Quality Assurance 12 Hrs  
Good Laboratory Practice, GMP, Overview of ICH Guidelines – QSEM, with special emphasis on Q-series guidelines.  
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.
2. cGMP guidelines according to schedule M, USFDA (inclusive 12 of CDER and CBER) Pharmaceutical Inspection Convention Hrs (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.
3. Analysis of raw materials, finished products, packaging 12 materials, in process quality control (IPQC), Developing Hrs 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.

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

#### REFERENCES

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



## HERBAL AND COSMETIC ANALYSIS (MPA 204T)

### Scope

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

### Objectives

At completion of this course student shall be able to understand

Determination of herbal remedies and regulations

Analysis of natural products and monographs

Determination of Herbal drug–drug interaction

Principles of performance evaluation of cosmetic products.

### THEORY

60 Hrs

1. Herbal remedies- Toxicity and Regulations: Herbs vs 12 Conventional drugs, Efficacy of herbal medicine products, Hrs Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.
2. Adulteration and Deterioration: Introduction, types of 12 adulteration/substitution of herbal drugs, Causes and Measure of Hrs 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.
3. Testing of natural products and drugs: Effect of herbal 12 medicine on clinical laboratory testing, Adulterant Screening using Hrs 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.

- 4 Herbal drug-drug interaction: WHO and AYUSH guidelines for 12 safety monitoring of natural medicine, Spontaneous reporting Hrs 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.

- 5 Evaluation of cosmetic products: Determination of acid value, 12 Hrs esterase 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.

#### 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, 4<sup>th</sup> edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICALS - I  
(MPA 205P)

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

Semester III  
MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

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

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

(Approved by AICTE, PCI and Affiliated to Osmania University)

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

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



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