Himachal Pradesh Technical University, Hamirpur (H.P.)

CURRICULUM (PCI)

MASTER OF PHARMACY (M.PHARMACY)

(PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE (PA&QA))

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Hamirpur - 177001

Teaching and Evaluation Scheme

SEMESTER- I (M. Pharmacy-Pharmaceutical Analysis & Quality Assurance)

S. N.	Cat.	Paper Code	Subject	L	T	P/D	Credits	Evaluation Scheme				
								Internal Assessment			ESE	Subject Total
								CT	TA	Total		
	Theory:											
1	PC	MPAQA 101T	Modern Pharmaceutical Analytical Techniques	4	0	0	4	15	10	25	75	100
2	PC	MPAQA 102T	Advanced Pharmaceutical Analysis And Quality Management	4	0	0	4	15	10	25	75	100
3	PC	MPAQA 103T	Quality Control And Quality Assurance	4	0	0	4	15	10	25	75	100
4	PC	MPAQA 104T	Herbal And Cosmetic Analysis	4	0	0	4	15	10	25	75	100
		Labs:										
1	PC	MPAQA 105P	Pharmaceutical Analysis And Quality Assurance Practicals-I	-	-	12	6	30	20	50	100	150
		----	Seminar/Assignment	-	7	-	4	-	-	-	-	100
Total				**16**	**7**	**12**	**26**					
	Total work Load=35						**Total Credit = 26**					

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Teaching and Evaluation Scheme

SEMESTER- II (M. Pharmacy-Pharmaceutical Analysis & Quality Assurance)

S. N.	Cat.	Paper Code	Subject	L	T	P/D	Credits	Evaluation Scheme				
								Internal Assessment			ESE	Subject Total
								CT	TA	Total		
	Theory:											
1	PC	MPAQA 201T	Advanced Instrumental Analysis	4	0	0	4	15	10	25	75	100
2	PC	MPAQA 202T	Modern Bio-Analytical Techniques	4	0	0	4	15	10	25	75	100
3	PC	MPAQA 203T	Pharmaceutical Validation	4	0	0	4	15	10	25	75	100
4	PC	MPAQA 204T	Pharmaceutical Manufacturing Technology	4	0	0	4	15	10	25	75	100
		Labs:										
1	PC	MPAQA 205P	Pharmaceutical Analysis And Quality Assurance – Practicals	-	-	12	6	30	20	50	100	150
			Seminar/Assignment	-	7	-	4	-	-	-	-	100
Total				**16**	**7**	**12**	**26**					**650**

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III Semester -Course of study for M. Pharm.
(Common for All Specializations)

S. N.	Category	Paper Code	Subject	L	T	P/D	Credits	Evaluation Scheme				
								Internal Assessment			ESE	Subject Total
								CT	TA	Total		
	Theory:											
1		MRM 301T	Research Methodology and Biostatistics*	4	-	-	4	15	10	25	75	100
2			Journal club	1	-	-	1	-	-	25	-	25
3			Discussion / Presentation (Proposal Presentation)	2	-	-	2	-	-	50	-	50
4			Research Work	28	-	-	14	-	-	-	350	350
Total				**35**			**21**	-	-			**525**
	Total work Load=35						**Total Credit = 21**					

* Non University Exam

Course of study for M. Pharm. IV Semester
(Common for All Specializations)

S. N.	Category	Paper Code	Subject	L	T	P/D	Credits	Evaluation Scheme				
								Internal Assessment			ESE	Subject Total
								CT	TA	Total		
	Theory:											
2			Journal club	1	-	-	1	-	-	25	-	25
3			Discussion / Presentation (Proposal Presentation)	3	-	-	3	-	-	75	-	75
4			Research Work	31	-	-	16	-	-	-	400	400
Total				**35**	-	-	**20**	-	-	-	-	-
	Total work Load=35						**Total Credit = 20**					

* Non University Exam

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Semester Wise Credit 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

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PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

MPAQA 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(Common for All PG Pharmacy Courses)

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

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,

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

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	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. 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 c. **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	11
II	**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-	11

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	Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.	
III	**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	**11**
IV	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	**11**
V	a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis iv) Zone electrophoresis v) Moving boundary electrophoresis vi) Iso electric focusing b. **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 Xray diffraction. c. **Immunological assays** : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	**16**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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MPAQA 102T. ADVANCED PHARMACEUTICAL ANALYSIS AND QUALITY MANAGEMENT

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

Scope: This course is designed to impart knowledge on analysis of new drugs and dosage forms as per Regulatory requirements. To impart the knowledge concerned with quality management of process and product.

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

- Modern Analysis method protocols
- Basic principles of Immunoassays
- The TQM aspects in a pharmaceutical industry
- To understand the scope IPQC applicable to Pharmaceutical industries

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	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, Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	16
II	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.	10
III	Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	10
IV	Pharmaceutical quality Management: Basics of Quality Management, Total Quality	

	Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	**12**
V	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective &Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	**12**

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.
9. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.

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10. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
11. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
12. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
13. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.
14. Methods of sampling and microbiological examination of water, first revision, BIS
15. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
16. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
17. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
18. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
19. ICH Guidelines for impurity profiles and stability studies.

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MPAQA 103T. QUALITY CONTROL AND QUALITY ASSURANCE

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

Scope: This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It covers the important aspectslikecGMP, QC tests, documentation, quality certifications, GLP and regulatoryaffairs.

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 toPharmaceutical industries
- To understand the responsibilities of QA & QC departments

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	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.	12
II	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, drugindustry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.	12
III	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)Purchase	12

	specifications and maintenance of stores for rawmaterials. 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.	
IV	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention andretrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan andreports. Specification and test procedures, Protocols and reports.Distribution records. Electronic data.	**12**
V	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.	**12**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures ofIndia, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines andRelated 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 Methodsof Analysis and Quality specification for Pharmaceutical Substances,Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, MarcelDekker Series, 1989.
7. ICH guidelines

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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 qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturersand Their Suppliers, Sixth Edition, (Volume 1 - With Checklists andSoftware Package).Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley& Sons; 2008.

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MPAQA 104T. HERBAL AND COSMETIC ANALYSIS

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

Scope: This course is designed to impart knowledge on analysis of herbal products.Regulatoryrequirements, herbal drug interaction with monographs.Performance evaluation of cosmetic products is included for the betterunderstanding 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.

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.	12
II	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.	12
III	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.	**12**
IV	Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.	**12**
V	. 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.	**12**

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 AshutoshKar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P.Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher'sPerfumes,Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook ofCosmetic Science and Technology, 3rd Edition,

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MPAQA 105P. PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE PRACTICALS-I

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
0	0	12	6	50	100	150	6 hours

1. Analysis of Pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
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. Development of Stability study protocol
10. Testing of related and foreign substances in drugs and raw materials
11. Colorimetric determination of drugs by using different reagents
12. Imupurity profiling of drugs
13. Determination of saponification value, Iodine value, Peroxide value, Acidvalue in herbal products
14. Determination of fat content and rancidity in herbal products
15. Analysis of vitamin in pharmaceutical formulations
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

2nd Semester

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MPAQA 201T. ADVANCED INSTRUMENTAL ANALYSIS

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

Scope: This subject deals with various hyphenated analytical instrumental techniquesfor identification, characterization and quantification of drugs. Instruments dealtare 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 organiccompounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plateheight, resolution, band broadening, pumps, injector, detectors,columns, column problems, gradient HPLC, HPLC solvents,trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations,revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.	12
II	Bio-chromatography: Size exclusion chromatography, ionexchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobilephases. Gas chromatography: Principles, instrumentation, derivatization, head space	12

	sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.	
III	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.	**12**
IV	Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact,chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis.Mass analysers (Quadrpole, Time of flight,FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems(Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.	**12**
V	. 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-Spincoupling, 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-Dand 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy.LC-NMR hyphenations.	**12**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P DSethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

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MPAQA 202T. MODERN BIO-ANALYTICAL TECHNIQUES

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

Scope: This subject is designed to provide detailed knowledge about the importance ofanalysis 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.

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	Extraction of drugs and metabolites from biological matrices:General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines.	12
II	Biopharmaceutical Consideration:Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.	12
III	Pharmacokinetics and Toxic kinetics: Basic consideration, Drug interaction (PK-PD interactions), Theeffect 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 toxic kinetic studies. LC-MS in	12

	bioactivity screening and proteomics.	
IV	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 cellviability assays (MTT assays), Principles and applications of flowcytometry.	**12**
V	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.	**12**

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 LBertholf, 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.

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MPAQA 203T. PHARMACEUTICAL VALIDATION

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

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

Objectives : At completion of this course, it is expected that students will be able to understand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	**Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation.Calibration of weights and measures. Advantages of Validation, scope of Validation,Organization for Validation, Validation Master plan, Types ofValidation, 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).	10
II	**Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and	

	Tray dryers, Tablet Compression(Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.	**10**
III	**Qualification of laboratory equipments:** Hardness tester,Friability test apparatus, tap density tester, Disintegration tester,Dissolution test apparatusValidation of Utility systems: Pharmaceutical water system &pure steam, HVAC system, Compressed air and nitrogen.	**10**
IV	**Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment,Cleaning of Facilities. Cleaning in place (CIP).Validation of facilities in sterile and non-sterile plant.Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP	**20**
V	**General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP),Intellectual Property Rights (IPR); Economic importance,mechanism for protection of Intellectual Property – patents,Copyright, Trademark; Factors affecting choice of IP protection;Penalties for violation; Role of IP in pharmaceutical industry;Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee;Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	**10**

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REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House,Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood Internationalpublishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton&Agalloco,(Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries, Syed ImtiazHaider
7. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, 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 byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. InformaHealthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice forPharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing.Interpharm Press

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MPAQA 204T. PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

Scope: This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives : At completion of this course it is expected that students will be able tounderst and,

1. The common practice in the pharmaceutical industry developments, plant layout and production planning
2. Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
I	Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.Production planning: General principles, production systems,calculation of standard cost, process planning, routing, loading,scheduling, dispatching of records, production control.	12
II	Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder,Solution (Small Volume & large Volume).Advanced sterile product manufacturing technology : Area planning&	12

	environmental control, wall and floor treatment,fixtures and machineries, change rooms, personnel flow, utilities& utilities equipment location, engineering and maintenance.Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet,Needle Free Injections, and Form Fill Seal Technology (FFS).Lyophilization technology: Principles, process, equipment.	
III	Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets(compressed & coated), Capsules (Hard & Soft).Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process,granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.Coating technology: Process, equipments, particle coating,fluidized bed coating, application techniques. Problems encountered.	**12**
IV	Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used,Drug plastic interactions, biological tests, modification of plasticsby drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil /plastic pouches, bottle seals, tape seals, breakable seals andsealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility,transit worthiness of package, Stability aspects of packaging.Evaluation of stability of packaging material.	**12**
V	Quality by design (QbD) and process analytical technology(PAT): Current approach and its limitations. Why QbD is required,Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA,CPP, RLD, Design space, Design of Experiments, RiskAssessment and mitigation/minimization.Quality by Design,Formulations by Design, QbD for drug products, QbD for DrugSubstances, QbD for Excipients, Analytical QbD. FDA initiative onprocess	**12**

	analytical technology. PAT as a driver for improvingquality and reducing costs: quality by design (QbD), QA, QC andGAMP. PAT guidance, standards and regulatory requirements.	

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrialpharmacy 3rded., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms:tablets Vol. I-III,2 nded., CBS Publishers & distributors, New Delhi, 2005.
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5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Goodmanufacturing of pharmaceuticals (A Plan for total quality control) 3rdEdition.Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication.Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office,London, 2008.
8. United States Pharmacopoeia. United States PharmacopeialConvention,Inc, USA, 2003.
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10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. InformaHealth care USA Inc. New york.
11. Shaybe Cox Gad.Pharmaceutical Manufacturing Handbook. John Willeyand Sons, New Jersey, 2008.

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MPAQA 205P. PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE – PRACTICALS

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
0	0	12	6	50	100	150	6 hours

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 techniquesand 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/Bioanalyticalmethodvalidation.
11. Protocol preparation for the conduct of BA/BE studies according toguidelines.
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. Validation of an analytical method for a drug
17. Validation of a processing area
18. Qualification of at least two analytical instruments
19. Cleaning validation of one equipment
20. Qualification of Pharmaceutical Testing Equipment (Dissolution testingapparatus, Friability Apparatus, Disintegration Tester)
21. Case study on application of QbD

3rd SEMESTER

MRM301T - RESEARCH METHODOLOGY & BIOSTATISTICS

Teaching and Examination Scheme:

Teaching Scheme			Credits	Marks			Duration of End Semester Examination
L	T	P	C	Sessional	End Semester Exam	Total	
4	0	0	4	25	75	100	3 hours

COURSE CONTENT

UNIT	CONTENT	No. of Hrs.
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.	12
II	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12
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.	12
IV	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and	12

	training, transport of lab animals.	
V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**12**

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