GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program	Master of Pharmacy (M.Pharm)	Branch	Quality Assurance	Semester	1	Version	2.0.0.0
Effective from	2018-19	Effective for batches admitted onwards		2018-19			

S. N	Subject Code	Subject Name	Theory / Practical/ Seminar	Teaching Scheme		Examination Scheme			
				Credit	Hours Per Week	Marks			Total Marks
						CE	SE	ES	
1	MAT101T	Modern Pharmaceutical Analytical Techniques	Theory	4	4	10	15	75	100
2	MQA102T	Quality Management System	Theory	4	4	10	15	75	100
3	MQA103T	Quality Control and Quality Assurance	Theory	4	4	10	15	75	100
4	MQA104T	Product Development and Technology Transfer	Theory	4	4	10	15	75	100
5	MQA105P	Quality Assurance Practical - I	Practical	6	12	20	30	100	150
6	MEL106S	Seminar	Seminar	4	8	-	-	100	100
			Total	26	36	60	90	500	650

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FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Quality Assurance					
Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MAT101T	Subject Name		Modern Pharmaceutical Analytical Techniques						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

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

Learning Outcome:

- Knowledge of molecular and atomic spectroscopic methods of analysis
- Understand various separation techniques for the analysis of drugs and biomolecules
- Application of instrumental techniques for qualitative and quantitative analysis of organic substances
- Analyse and select best suitable analytical techniques for the estimation of drugs and pharmaceuticals
- Evaluation of analytical methods used for thermal analysis
- Create analytical skills for identification and quantification of drugs using modern analytical techniques

Syllabus- Theory

Unit	Content	Hrs
1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV/Visible Spectroscopy	08
2	Spetrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer	06
3	Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	08
4	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	05
5	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy	07
6	Mass Spectroscopy: Principle, Theory, Instrumentation, 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	05
7	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	10
8	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) 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 X-ray diffraction.	07
9	Thermal Analysis: Polymer behavior, factors affecting and instrumentation, and working, application of TGA	04

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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Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MQA102T	Subject Name		Quality Management System						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Learning Outcome:

- Knowledge about the customer expectations in the quality pharmaceutical product.
- Understand the quality parameters and quality attributes in Pharmaceutical industry sectors.
- Apply the knowledge on how to perform stability testing of drug and drug substances as per ICH guidelines.
- Applications of the statistical approaches for quality.
- By studying and practicing the guidelines ISO, NABL and other regulatory agencies student will be able to evaluate and predicts the current need of changes.
- The subject will afford methodology in the regulatory body requirements for the import and export pharmaceutical products.

Syllabus- Theory

Unit	Content	Hrs
1	Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimizing costs, Preventing cost of quality.	12
2	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
3	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
4	Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12
5	Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	08

6	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	04

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.

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Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MQA103T	Subject Name		Quality Control and Quality Assurance						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

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

Learning Outcome:

	knowledge about analysis of raw materials, finished pharmaceuticals, packaging materials, and perform In process quality control and finished products quality control testing as per IP, BP.
	Understand and outline about QC, QA concepts as well as GMP, GLP, CPCSEA, ICH-QSEM guidelines.
	Applicability of GMP guidelines as per WHO, US-FDA, EMEA to quality testing, management, manufacturing, and the control of pharmaceutical products.
	Analyse and interpret certain GMP aspects like training, hygiene, records, maintenance, sanitation, utilities and maintenance of sterile areas, control of contamination etc.
	Evaluate all documentation like SOPs, reports, forms and formats in pharmaceutical industry.
	Create a skill for good manufacturing practices, good laboratory practices and QC QA principles in pharmaceutical industries and R & D centre.

Syllabus- Theory

Unit	Content	Hrs
1	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries 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. CPCSEA guidelines.	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12
3	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 dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12
4	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	12
5	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste	12

	and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	

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

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Program	Master of Pharmacy			Branch/Spec.	Quality Assurance					
Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MQA104T	Subject Name		Product Development and Technology Transfer						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Learning Outcome:

- Knowledge of regulatory principles and requirements of drug discovery and developments
- Understand the concept of pre-formulation approaches and protocol for various formulations
- Application of pilot plants scale up and pre-formulation studies in pharmaceutical product development
- Analyse, optimize and select suitable technology transfer methodology for research and development
- Evaluation of pharmaceutical packaging materials
- Create skills to handle opportunities and challenges in pharmaceutical product development

Syllabus- Theory

Unit	Content	Hrs
1	Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA	12
2	Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co- solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development	12
3	Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12
4	Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12
5	Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12

References

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.

6	Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7	Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8	Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9	The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10	Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

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Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MQA105P	Subject Name		Quality Assurance Practical - I						
Teaching scheme		Examination scheme								
Credit	6		CE	SE	ES	Total		SE	ES	
Hours	12	Marks	20	30	100	150	Duration	1 hr.	3 hr.	

Learning Outcome

	Gain basic practical knowledge relevant to the analysis of sample.
	Understand preformulation studies, IPQC, FPQC, quality control testing of samples.
	Apply the skill to perform quality control and tools of quality assurance in pharmaceutical industries.
	Analyse physicochemical properties like solubility, pKa and log P of drugs.
	Evaluate and describe implementation of principles like TQM, Six Sigma, Change control/ Deviation Management, Out of Specifications (OOS), Out of Trend (OOT), Corrective & Preventive Actions (CAPA) in pharmaceutical industries.
	Perform stability studies and stability protocol and other quality control testing to prove quality of drugs by themselves.

List of Practicals

PART A:

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 other applications of UV spectrophotometry
4. Experiments based on different chromatographic techniques
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

1. Case studies on
   a. Total Quality Management
   b. Six Sigma
   c. Change Management/ Change control. Deviations,
   d. Out of Specifications (OOS)
   e. Out of Trend (OOT)
   f. Corrective & Preventive Actions (CAPA)
   g. Deviations
2. Development of Stability study protocol
3. Estimation of process capability
4. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
5. Assay of raw materials as per official monographs
6. Testing of related and foreign substances in drugs and raw materials
7. To carry out pre formulation study for tablets, parenterals (2 experiment).
8. To study the effect of pH on the solubility of drugs, (1 experiment)
9. Quality control tests for Primary and secondary packaging materials
10. Accelerated stability studies (1 experiment)
11. Improved solubility of drugs using surfactant systems (1 experiment)
12. Improved solubility of drugs using co-solvency method (1 experiment)
13. Determination of Pka and Log p of drugs.

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Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MEL106S	Subject Name		Seminar						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	8	Marks	-	-	100	100	Duration	-	3 hr.	
Pre-requisites										
Nil										
Scope and Objectives:										
	• To develop know how of the latest development in the area of pharmaceutical science. • To develop the presentation skill for the information collected and compilated in the form of seminar.									
Learning Outcome:										
	Knowledge of the latest development in the area of pharmaceutical sciences									
	Understand the use of the library and internet resources for the referencing and literature purpose									
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way									
	Analyse the problems and strengthen ability for presentations and defending the viva voce									
	Evaluate the hypothesis, study design, method and results in a systemic manner									
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion									