Program	Master of Pharmacy (M.Pharm)	**Semester - 1**
Type of Course	-	
Prerequisite		
Course Objective	-	
Effective From A.Y.	2023-24	

Teaching Scheme (Contact Hours)				Examination Scheme				
				Theory Marks		Practical Marks		
Lecture	Tutorial	Lab	Credit	External Marks (T)	Internal Marks (T)	External Marks (P)	Internal Marks (P)	Total Marks
4	-	-	4	75	25	-	-	100

SEE *- Semester End Examination,* ***CIA*** *- Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)*

Course Content

T - Teaching Hours | **W** - Weightage

Sr.	Topics	T	W
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, Optimising costs, Preventing cost of quality.	12	20
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	20
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	20
4	**Drug Stability**	12	20

Course Content

T - Teaching Hours | **W** - Weightage

Sr.	Topics	T	W
	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.		
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.	8	14
6	**Regulatory Compliance & Benchmarking** 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.	4	6
	Total	**60**	**100**

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application	Analyze	Evaluate
Weightage	30	35	20	10	5

NOTE : This specification table shall be treated as a general guideline for the students and the teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes

At the end of this course, students will be able to:	
CO1	Basic knowlegde of quality management principles and documentation Practices for Pharmaceutical industry.
CO2	Understanding of basics of quality certifications, Regulatory compliance and concepts of ISO, ICH, GMP & SPC

Reference Books

1.	**Corporate Culture and the Quality Organization** By James W. Fairfield- Sonn | Quorum Books | 2001
2.	**Understanding Managing & Implementing Quality Frame work Techniques & Cases (TextBook)** By Jiju Antony and David Preece | Routledge Taylor & Francis Group | Special Indian Edn., Pub. Year 2018
3.	**Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results** By Al Endres, Wiley
4.	**Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000:** By he CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, | 2001
5.	**Juran's Quality Quality Handbook – The complete guide to Performance Excellence (TextBook)** By Joseph M. Juran Joseph A Defeo | The Mc Graw- Hill, companies. Education | 6th Edn, Pub. Year 2010
6.	**The Quality Management Source Book - An International guide to Materials & Resources (TextBook)** By Christine Avery and Diane Zabel | Routledge Taylor & Francis Publications | Special Indian Edn., Pub. Year 2018
7.	**Quality Assurance and Quality Management in Pharmaceutical Industry** By Anjaneyulu R. Marayya. | Pharma Book Syndicate | 1st Edn., Pub. Year 2005
8.	**Root cause Analysis, the core problem solving and Corrective Action** By Duke Okes | ASQ Quality Press | 1st Edn., Pub. Year 2009
9.	**A Text book of Quality Management System** By Dr. Md. Rageeb Md. Usman, Rahul Gawali, Snehal Abhang, Dr. Bharat V. Jain | Pee Vee S.Vikas & Company | 1st Edn., Pub. Year 2021
10.	**The Quality Toolbox** By Nancy R. Tague | ASQ Publications | Second Edition