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	**UNIT I** a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION),drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	**15**	**25**
2	**UNIT II** CMC, post approval regulatory affairs Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	**15**	**25**
3	**UNIT III** Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	**15**	**25**
4	**UNIT IV** Clinical trials Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	**15**	**25**
	Total	**60**	**100**

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application
Weightage	50	25	25

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	Understanding the concept of innovator and generic drug development.
CO2	To know regulatory guidelines for product approval and post approval requirements of variour countries.
CO3	To know and understand the concept of clinical trial requirements and pharmacovigilence.

Reference Books

1.	**Generic Drug Product Development (TextBook)** By Leon Sharge | Marcel Dekker series | Vol. 3
2.	**The Pharmaceutical Regulatory Process (TextBook)** By Ira R. Berry and Robert P.Martin | Informa Health care Publishers | Second
3.	**New Drug Approval Process** By Richard A Guarino | Drugs and the Pharmaceutical Sciences | Fifth
4.	**Guidebook for drug regulatory submissions** By Sandy Weinberg | John Wiley & Sons.Inc
5.	**FDA regulatory affairs** By Douglas J. Pisano | David Mantus
6.	**Clinical Trials and Human Research** By y Fay A. Rozovsky and Rodney K. Adams