Program	Master of Pharmacy (M.Pharm)	**Semester - 2**
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 1** Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12	20
2	**UNIT 2** Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12	20
3	**UNIT 3** Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12	20
4	**UNIT 4** IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	12	20
5	**UNIT 5** Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12	20
	Total	60	100

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding
Weightage	50	50

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	Understand and learn the toxicity studies as per various international regulatory bodies guidelines.
CO2	Demonstrate the practical skills and learning ethical guidelines for preclinical & clinical studies.

Reference Books

1.	**Hand book on GLP, Quality practices for regulated non-clinical research and development**
2.	**Schedule Y Guideline: drugs and cosmetics (second amendment) rules (TextBook)** By Government of India, Ministry of Health and Family Welfare, Pub. Year 2005
3.	**Drugs from discovery to approval**
4.	**Animal Models in Toxicology**
5.	**OECD test guidelines**
6.	**Principles of toxicology** By Karen E. Stine, Thomas M. Brown
7.	**Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals**