

Subject Code: MPL202T	Subject Title: Pharmacological and Toxicological Screening Methods-II
Pre-requisite Subject	-NONE-

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Course Objectives: After completion of course student is able:

1. To explain the various types of toxicity studies.
2. To appreciate the importance of ethical and regulatory requirements for toxicity studies.
3. To demonstrate the practical skills required to conduct the preclinical toxicity studies.

Teaching and Examination Scheme:

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)		
Lecture	Tutorial	Practical	Credit	Theory (T)		Total (Marks)
				University Assessment	Continuous Assessment	
4	-	-	4	75	25	100

Subject Contents:

Sr. No.	Topic	Total Hours	Weight (%)
1	UNIT I 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 II 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 III Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity 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 IV 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 V Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12	20

References:

Reference Books:

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glphandbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
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 (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)