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** 1. Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process.	10	20
2	**UNIT 2** Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	10	20
3	**UNIT 3** Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	10	20
4	**UNIT 4** Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	10	20
5	**UNIT 5** Methods, ADR reporting and tools used in Pharmacovigilance, International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, Vigi Flow, Statistical methods for evaluating medication safety data.	10	10
6	**UNIT 6**	10	10

Course Content

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

Sr.	Topics	T	W
	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology		
	Total	**60**	**100**

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application
Weightage	40	40	20

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 regulatory requirements for conducting clinical trial and clinical trial design.
CO2	understand roles of trial personnels and clinical trial documents.
CO3	Understand about ADR and pharmacovigilance.

Reference Books

1.	**Textbook of Clinical Trials (TextBook)** By David Machin | John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester | 1, Pub. Year 2004
2.	**Clinical data management** By edited by Richard Rondel, Sheila Varley, Colin Webb | Chichester: Wiley, c2000 | 2
3.	**Handbook of clinical Research** By Julia Lloyd and Ann Raven Ed | Churchill Livingstone; 1994, Pub. Year 1994
4.	**Principles of Clinical Research (Indian Edition)** By Edited by Ignazio Di Giovanna and Gareth Hayes
5.	**Good Clinical Practice guidelines** By CDSCO-Guidelines
6.	**INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE** By ICH-Guidelines, Pub. Year 2023