MRSPTU COURSE PLAN 2016 BATCH
COURSE CODE: MPHA2-210 COURSE: CLINICAL RESEARCH AND PHARMACOVIGILANCE

Class: M.Pharm. (Pharmacology) **Semester:** II **Session:** 2016-17 **Batch**: 2016

Course: Clinical research and Pharmacovigilance **Course Code**: MPHA2-210

Name of Course Coordinator: Dr. Anjana Bali

Designation: Associate Professor & Head, Department of Pharmacology

College: Akal College of pharmacy and technical education, Mastuana sahib, Sangrur

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Syllabus for 1st Mid Semester Test	Unit I-Regulatory perspectives of clinical trials Unit II-Clinical Trials-Types/Design
Syllabus for 2nd Mid Semester Test	Unit-III- Pharmacovigilance/WHO Unit-IV-Methods, ADR reporting and Tools used in Pharmacovigilance
1st Assignment	Date of Issue: 28th Feb, 2017 Last date for Submission: 10th March, 2017
2nd Assignment	Date of Issue: 13th March, 2017 Last date for Submission: 22nd March, 2017
3rd Assignment	Date of Issue: 23rd March, 2017 Last date for Submission: 31st March, 2017
4th Assignment	Date of Issue: 3rd April, 2017 Last date for Submission: 15th April, 2017

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M. PHARMACOLOGY (SECOND SEMESTER) **CLINICAL RESEARCH AND PHARMACOVIGILANCE**		
Code	**Title**	**Marks**
MPHA2-210	**Informed consent (IF)** • **Ethical guidelines governing informed consent process** • **Structure and consent of informed consent process**	**15**
	Clinical trials • **Phases of Clinical trials** • **Clinical study design** • **Clinical trial documentation**	**15**
	Pharmacovigilance • **Practice of Pharmacovigilance in the pharmaceutical industry.** • **Drug regulation of Pharmacovigilance**	**15**
	Adverse Drug Reaction • **Guidelines for adverse drug reporting** • **Management of ADR**	**15**

Date: 21st Feb, 2017 Signature

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