



HINDU COLLEGE OF PHARMACY, GUNTUR

Department of Pharmacology

CERTIFICATE COURSE

Title: Good Clinical Practice (GCP) guidelines

Code: VACCL02

Year of Introduction: 2018

About the course (Description):

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

CONTENTS:

No. of Hrs. 30

Unit 1:

- Introduction
- Principles of ICH- GCP
- IRB/IEC
- Investigator
- Sponsor

Unit 2:

- Clinical trial protocol
- Protocol amendments
- Investigators Brochure

Unit 3:

- Essential documents for the conduct of a clinical trial

Course Outcomes:

Good clinical practice guidelines helps the students in gaining the skills of design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials.

SCHEDULE:

S.No	Date	Time	Resource Persons
1	4-2-2018	10.00 AM- 1.00 PM & 2.00-5.00 PM	N.Tulsi Uma Rani & P.Mounica, HCOP, Guntur
2	11-2-2018	10.00 AM- 1.00 PM & 2.00-5.00 PM	N.Tulsi Uma Rani & P.Mounica, HCOP, Guntur
3	18-2-2018	10.00 AM- 1.00 PM & 2.00-5.00 PM	N.Tulsi Uma Rani & P.Mounica, HCOP, Guntur
4	4-3-2018	10.00 AM- 1.00 PM & 2.00-5.00 PM	N.Tulsi Uma Rani & P.Mounica, HCOP, Guntur
5	11-3-2018	10.00 AM- 1.00 PM & 2.00-5.00 PM	N.Tulsi Uma Rani & P.Mounica, HCOP, Guntur

Person Incharge (Coordinator):

Name	Address	e-mail	Phone No.
Dr.D.BrahmaSrinivasaRao	Professor & HOD Dept. of Pharmacology, HCOP, Guntur	desu.brahmasrinivasarao@gmail.com	9494539980

Coordinator

PRINCIPAL