



RAGHU COLLEGE OF PHARMACY

Dakamarri, Bheemunipatnam Mandal, Visakhapatnam - 521162.

(Affiliated to ANDHRA UNIVERSITY, VISAKHAPATNAM)

COURSE PLAN- One copy to be submitted to the HOD one week before commencement of the Semester

Subject Code	Name of the Subject	Class/ Semester	Name of the Faculty/ Designation	No. of Students	Total periods per Semester / Year	
					Lectures	Tutorials
BP 702T	Pharmaceutical Regulatory Science	IV/IV B.Pharmacy- II Sem Sec A & B	Dr. G.Gowri Associate Professor	80	25	5

Lecture No.	Topic	E.T. Gadgets used, if any (LCD/OHP/ Charts/Models)	Date on which completed*
L1	Introduction	PPT	19-03-24
L2	Stages of Drug Discovery	PPT	21-03-24
L3	Stages of Drug Discovery	PPT	22-03-24
L4	Drug Development Process	PPT	23-03-24
L5	Drug Development Process	PPT	26-03-24
L6	Pre-Clinical Studies	PPT	27-03-24
L7	Non-Clinical Activities	PPT	28-03-24
T1	Tutorial		30-03-24
L8	Clinical Studies Concept of Generics	PPT	2-04-24
L9	Innovator and Generics	PPT	3-04-24
L10	Concept of Generics	PPT	4-04-24
T2	Tutorial		6-04-24
L11	Generic Drug Product Development	PPT	8-04-24
L12	Revision		10-04-24
L13	Developing Clinical Trial Protocols	CHALK & TALK	12-04-24
L14	Institutional Review Board / Independent Ethics Committee	CHALK & TALK	18-04-24
L15	Formation and Working Procedures	CHALK & TALK	19-04-24
L16	Informed Consent Process and Procedures	CHALK & TALK	25-04-24
L17	GCP Obligations of Investigators	CHALK & TALK	26-04-24
L18	Sponsors & Monitors	CHALK & TALK	2-05-24
L19	Managing And Monitoring Clinical Trials	CHALK & TALK	3-05-24
L20	Pharmacovigilance - Safety Monitoring in Clinical Trials	CHALK & TALK	20-06-24
L21	Regulatory Concepts : Basic Terminology	CHALK & TALK	21-06-24
T3	Tutorial		22-06-24
L22	Guidance, Guidelines	CHALK & TALK	27-06-24
T4	Tutorial		29-06-24
L23	Regulations	CHALK & TALK	28-06-24
L24	Laws And Acts	CHALK & TALK	04-07-24
L25	Orange Book	CHALK & TALK	05-07-24
T5	Tutorial		06-07-24

Signature of the Faculty Member

Dr. G. Gowri

Jayashankar B. S.
Signature of the Principal