



C. U. SHAH UNIVERSITY

Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutical Quality Assurance

SEMESTER: III

CODE: MRM301T

NAME: Research Methodology and Biostatistics (Theory)

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credit	Evaluation Scheme								Total
		Th	Tu	Pr	Total		Theory				Practical				
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MRM301T	Research Methodology and Biostatistics (Theory)	4	0	0	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

UNIT	COURSE CONTENT (60 Hours)	HR.
I	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	12
II	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12
III	Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	12
IV	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	12
V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	12
Total		60