

Nirma University

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Regulatory Affairs)

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/ PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA302T	Journal Club	1	-	-	1	-	-	1.0	-	-
3	MRA303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MRA304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	7	28		21					

* Non University Examination (NUE)

L: Lectures, P/T: Practicals/Tutorial, C: Credits

LPW: Laboratory / Project Work

SEE: Semester End Examination

CE: Continuous Evaluation

w.e.f. academic year 2018-2019 and onward

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm)
(Semester - III)

L	T	P	C
4	-	-	4

Course Code	MRM301T
Course Title	Research Methodology & Biostatistics

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus:

Teaching hours: 60 Hours

UNIT I

15 Hours

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II

20 Hours

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, application based case studies.

UNIT III

10 Hours

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.

UNIT IV

05 Hours

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, Import of animals.

UNIT V

10 Hours

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested Readings[^]: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education*. New Delhi, Prentice Hall of India Pvt. Ltd.
2. Halton, M., *Presentation Skills*. Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright*. McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering*. St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing*. John Wiley & Sons.

L= Lecture, T= Tutorial, P= Practical, C= Credit

[^] this is not an exhaustive list
