Table 13: Course of study for M. Pharm III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		**35**	**21**

Non-University Exam

Table 14: Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		**35**	**20**

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MRM 301T - Research Methodology & Biostatistics

Unit	Contents
UNIT – 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.
UNIT – 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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.
UNIT – 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.
UNIT – 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.
UNIT – V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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Sl. No	References
1	Kothari C.R. Research Methodology: Methods and Techniques, New Age International Publishers, New Delhi.
2	Greenhalgh T. How to Read a Paper: The Basics of Evidence-Based Medicine, BMJ Books.
3	Hulley S.B., Cummings S.R., Browner W.S., Grady D.G., Newman T.B. Designing Clinical Research, Lippincott Williams & Wilkins.
4	Dawson B., Trapp R.G. Basic & Clinical Biostatistics, McGraw Hill.
5	Daniel W.W. Biostatistics: A Foundation for Analysis in the Health Sciences, Wiley.
6	Snedecor G.W., Cochran W.G. Statistical Methods, Oxford & IBH Publishing.
7	Armitage P., Berry G., Matthews J.N.S. Statistical Methods in Medical Research, Blackwell Science.
8	ICH Harmonised Tripartite Guideline for Good Clinical Practice (ICH-GCP E6).
9	Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants.
10	CPCSEA Guidelines for Laboratory Animal Facility, Government of India.
11	World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.
12	OECD Guidelines for the Testing of Chemicals.
13	Altman D.G. Practical Statistics for Medical Research, Chapman and Hall.
14	Bland M. An Introduction to Medical Statistics, Oxford University Press.

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