Table – 12: 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 – 13: 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

Table – 14: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

M. PHARM – III SEMESTER

SUBJECT : MRM 301T - RESEARCH METHODOLOGY & BIOSTATISTICS

(COMMON PAPER)

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, Report writing and presentation of data, plagiarism and publication ethics in research.

UNIT – II Biostatistics: Definition, Introduction to biostatistics, types of sampling techniques, 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: NEW DRUGS AND CLINICAL TRIALS(NDCT) RULES -2019:
Introduction to NDCT-2019 rules, Central Licensing Authority, ethics committee for clinical trial, BA-BE study and biomedical research. Clinical trial and bioequivalence study of new drug or investigational new drug. Compensation in case of injury or death in clinical trial and bioequivalence study of new drug or investigational new drug. Schedule-I to VIII oF NDCT-2019 RULES.

UNIT – IV CCSEA guidelines for laboratory animal facility: Principle of 5Rs, Composition and functions of institutional animal ethics committee (IAEC), 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 lhusbandry, 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.
Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality and futility.