# M.Pharm Syllabus

## Semester 03

### Pharmaceutical Biotechnology

### Subjects


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# MRM301T - Research Methodology and Biostatistics

## Theory

### 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.

# Research and Academic Activities

## Research Work

- Journal club.
- Research work.
- Discussion and proposal presentation.
- Research objectives and methodology.
- Results and discussion.
- Conclusions and outcomes.

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