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| Program | Master of Pharmacy (M.Pharm) | Semester - 3 |
| Type of Course | - | |
| Prerequisite | | |
| Course Objective | - | |
| Effective From A.Y. | 2024-25 | |

| Teaching Scheme (Contact Hours) | | | | Examination Scheme | | | | |
|---------------------------------|----------|-----|--------|--------------------|--------------------|--------------------|--------------------|-------------|
| Lecture | Tutorial | Lab | Credit | Theory Marks | | Practical Marks | | Total Marks |
| | | | | External Marks (T) | Internal Marks (T) | External Marks (P) | Internal Marks (P) | |
| 4 | - | - | 4 | 75 | 25 | - | - | 100 |

SEE - Semester End Examination, **CIA** - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

| Course Content | | T - Teaching Hours W - Weightage | |
|----------------|---|------------------------------------|------------|
| Sr. | Topics | T | W |
| 1 | Unit 1 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 | 20 |
| 2 | Unit 2 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. | 15 | 25 |
| 3 | Unit 3 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. | 15 | 25 |
| 4 | Unit 4 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 | 20 |
| 5 | Unit 5 Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. | 6 | 10 |
| Total | | 60 | 100 |



Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

| Level | Remembrance | Understanding |
|-----------|-------------|---------------|
| Weightage | 50 | 50 |

NOTE : This specification table shall be treated as a general guideline for the students and the teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes

At the end of this course, students will be able to:

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| C01 | The students should understand the future trends and importance of statistical tools in research and pharmacy. |
| C02 | The students should be able to understand the regulatory perspectives of medical research |

Reference Books

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| 1. | RESEARCH METHODOLOGY (TextBook) By C R Kothari New Age International Publishers 5th |
| 2. | Pharmaceutical Experimental Design By Gareth A. Lewis, Didier Mathieu, Roger Phan-Tan-Luu CRC Press 1st |
| 3. | Pharmaceutical Statistics Practical and Clinical Applications By Sanford Bolton, Charles Bon CRC Press 5th, Pub. Year 2009 |