COURSE BOOK M. PHARM II YEAR

Pharmaceutics/Pharmacology/Pharmaceutical Quality Assurance) (Autonomous)

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CURRICULUM STRUCTURE & SYLLABUS

Effective from the Session: 2025-26

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Teaching Scheme of (M. Pharm II Year)

M. Pharm (Pharmaceutics/Pharmacology/Pharmaceutical Quality Assurance) 3rd Semester

S No.	Course Type	BOS	Subject Code	Subject Name	Academic Learning (AL)			Continuous Internal Examination (CIE)			End Semester Examination (ESE)	Total	Credit
					L	T	P	MSE	CA	TOTAL		CIE+ESE	Cr
1	M. Pharm	KSOP	MRM301T	Research Methodology and Biostatistics	4	0	0	15	10	25	75	100	**4**
2	M. Pharm	KSOP	MRM302T	Journal Club	1	0	0	-	25	25	-	25	**1**
Lab/Internship/Project Lab/Internship/Project Work/Workshop													
1	M. Pharm	KSOP	MRM303P	Discussion /Presentation (Proposal Presentation)	0	0	2	-	50	50	-	50	**2**
2	M. Pharm	KSOP	MRM304P (New)	Research Work*	0	0	28	-	350	350	-	350	**14**
Total Hours = 35(AL)+0(SL)= 35hrs.					**5**	**0**	**30**					**525**	**21**

M. Pharm (Pharmaceutics/Pharmacology/ Pharmaceutical Quality Assurance) 4th Semester

S No.	Course Type	BOS	Subject Code	Subject Name	Academic Learning (AL)			Continuous Internal Examination (CIE)			End Semester Examination (ESE)	Total	Credit
					L	T	P	MSE	CA	TOTAL		CIE+ESE	Cr
1	M. Pharm	KSOP	MRM401T	Journal Club	1	0	0	-	25	25	-	25	1
Lab/Internship/Project Work/Workshop													
1	M. Pharm	KSOP	MRM402P	Discussion / Presentation (Proposal Presentation)	0	0	3	-	75	75	-	75	3
2	M. Pharm	KSOP	MRM403P	Research Work and Colloquium*	0	0	31	-	200	200	200	400	16
3	M. Pharm	KSOP	--	Co-Curricular Activity (Participation in National /International level # conference /workshop/training/Publications (Scopus or Web of Science)	-	-	-	-	-	-	-	-	1/2
Total Hours = 35(AL)+0(SL)=35 hrs.					**1**	**0**	**34**	-				**500**	**21/22**

*** International conference held out side India.**
***The minimum credit point required for the award of M.Pharm Degree is 95.**

1. Theory Courses Detail Syllabus

Course Code: MRM301T	Course Name: Research Methodology & Biostatistics	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

Upon completion of the course the student shall be able to:

- Concise research questions and objectives that address gaps in current pharmaceutical knowledge.
- Comprehend various statistical techniques and their applications in analyzing research data.
- Justify sample sizes for various study designs.
- Design research plans to address ethical and scientific requirements.
- Demonstrate ethical responsibility in all aspects of research practices.
- Exhibit critical thinking in evaluating and interpreting scientific literature.

Course Outcome: After completion of the course, the student will be able to

1. Understand the knowledge and skills to design, conduct, and critically evaluate research studies, minimizing bias and errors through proper methodology and study design techniques.
2. Apply various statistical methods for analyzing sample data, enabling them to determine the significance of research findings.
3. Understand the ethical guidelines and regulatory standards for the care and management of laboratory animals, focusing on their welfare, proper facility maintenance, and scientific integrity in research.
4. Develop a comprehensive understanding of medical ethics and research practices.
5. Apply the ethical principles of the Declaration of Helsinki in the design, conduct, and oversight of medical research.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	-	3	3	-	-
CO2	2	-	3	3	-	-
CO3	2	-	3	3	-	-
CO4	2	-	3	3	-	-
CO5	2	-	3	3	-	-

Unit 1	General Research Methodology	10 hours

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 2	Biostatistics	10 hours

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 (Wilcoxen rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

Unit 3	Medical Research	10 hours

History, values in medical ethics, autonomy, beneficence, nonmaleficence, double effect, conflicts between autonomy and beneficence/nonmaleficence, 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 4	CPCSEA guidelines for laboratory animal facility	08 hours

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 5	Declaration of Helsinki	07 hours

History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

	Total Lecture Hours	45 hours

Textbook:

1. K R Sundaram, S N Dwivedi and V Sreenivas; Medical Statistics: Principles and Practice, 2nd Edition, Wolters Kluwer | Lippincott Williams and Wilkins India; 2014

2. Sanford Bolton; Pharmaceutical statistics- Practical and clinical applications, 5th Edition, Marcel Dekker Inc. New York: 2009
3. Bayya Subba Rao; Pharmaceutical Research Methodology and Biostatistics: Theory and Practice, PharmaMed Press / BSP Books India: 2020
4. Kothari,C.R and Gaurav Garg, Research: Methods and Techniques, 4th edition, New Age international publishers, New Delhi
5. Rao, Sundar S.S and Richard J: Introduction to Biostatistics,5thedition, PHI Publishers, New Delhi
6. Jann Hau, Steven J. Schapiro. Handbook of Laboratory Animal Science, Essential Principles and Practices. 4th Edition 2021, CRC Press, Boca Raton, Florida

Reference Books:

1. C. Gupta, Fundamentals of Statistics: 7th Edition, Himalaya Publishing House: 2017
2. Douglas C. Montgomery, Design and Analysis of Experiments 10th Edition, Wiley India: 2019
3. Pharmaceutical Statistics- Practical and Clinical Applications by Sanford Bolton, Marcel Dekker Inc. New York.
4. Design and Analysis of Experiments by R. Pannerselvam, PHI Learning Private Limited.

Mode of Evaluation

MSE		CA					ESE	Total
MSE1 30	MSE2 30	CA1 2	CA2 (ATT) 8					
Avg. of MSE1 & MSE2 and converted to 15		10					75	100

Annexure-1

Course Evaluation Structure M. Pharm 3rd Semester (Pharmaceutics/Pharmacology/Pharmaceutical Quality Assurance).

The evaluation of the M. Pharm (Pharmaceutics/Pharmacology/Pharmaceutical Quality Assurance) courses consists of both theory and lab assessments. The assessments are divided into multiple components as outlined below.

Theory Evaluation Plan

1. Continuous Assessment (CA) - Total Marks: 10
- CA-1: 2 Marks (Based on Assignment/Quiz/Class test/Presentation/Seminar/GD)
- CA-2: 8 Marks (Based on attendance)

2.Mid-Semester and End-Semester Evaluations - Total Marks: 25 Internal, 75 External
- MSE-1: 30 Marks
- MSE-2: 30 Marks } Average of MSE and converted to 15
- CA: 10 Marks (Based on continuous assessment)
- ESE: 75 Marks (externally evaluated)

3. Journal Club (MRM302T)
- CA-1: 15 Marks
- CA-2: 10 Marks
- Total: 25 Marks

Practical Evaluation Plan

1. MRM303P Discussion and Presentation
Continuous Assessment (CA) - Total Marks: 50
- CA: 50

2. MRM304P Research work*
- **Internal and External Marks Distribution: 350**

***Details of Research Work:**
- Literature review & Plan of work: 75
- Experimental methodology: 75
- Presentation Content: 50
- Communication skills: 50
- Conference Presentation: 50
- Regularities: 50

Annexure-2

Course Evaluation Structure M. Pharm 4th Semester (Pharmaceutics/Pharmacology/Pharmaceutical Quality Assurance).

The evaluation of the M. Pharm (Pharmaceutics/Pharmacology/Pharmaceutical Quality Assurance) courses consists of both theory and lab assessments. The assessments are divided into multiple components as outlined below.

Theory Evaluation Plan

1. **Journal Club (MRM401T)**
   - CA-1: 15 Marks
   - CA-2: 10 Marks
   - Total: 25 Marks

Practical Evaluation Plan:

1. **MRM402P Discussion/Presentation (Proposal Presentation)**
   - **Continuous Assessment (CA) - Total Marks: 75**

2. **MRM403P Research Work and Colloquium***
   Internal and External Marks Distribution: 200 + 200 = 400
   - **CA-1: 50**
   - **CA-2: 150***

*Experimental Work: 75
Presentation Content: 25
Communication Skills: 25
Conference Presentation/paper (Scopus/SCI/ESCI): 25
ESE final Viva-Voce of Project work by external examiner: 200