

Gujarat Technological University

M. Pharm. Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. _o.	Subject	Teaching Scheme		Marking Scheme			
		Credits		Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Research Methodology	07	-	80	20	--	--
2.	Subject Specialization of Paper – III	07	08	80	20	80	20
3.	Subject Specialization of Paper – IV	08	--	80	20	--	--
	Total	22	08				

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920001

Research Methodology

(Common to all discipline)

Theory

(Four hours per week, 7 credits)

1. Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, Historical descriptive, Basic applied and Patent oriented Research) objective of Research
2. Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey.
3. Selecting a problem and preparing Research proposals
4. Methods and tools use in research –
 - A. Qualitative studies, quantitative studies
 - B. Simple data organization descriptive data analysis,
 - C. Limitation & sources of Error
 - D. Inquiries in form of Questionnaire, etc.
5. Documentation-
 - A. "How" of documentation
 - B. Techniques of documentation
 - C. Importance of documentation
 - D. Use of computer packages in documentation.
6. The Research Report Paper writing/ thesis writing
Different parts of the Research paper
 1. Title –Title of project with authors name
 2. Abstract- Statement of the problem, Background list in brief and Purpose and scope.
 3. Key Words.
 4. Methodology-subject, apparatus, instrumentation & procedure.
 5. Results- tables, graphs, figures & statistical presentation
 6. Discussion support or non support of hypothesis, practical & theoretical Implications
 7. Conclusion
 8. Acknowledgements.
 9. References
 10. Errata
 11. Importance of Spell check for entire project
 12. Uses of footnotes
7. Presentation (especially for oral presentation)
Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire
8. Cost analysis of the project – cost incurred on raw materials-
Procedure, instrumentations and clinical trials.
9. Sources for procurement research grants – international agencies, Government and private bodies.
10. Industrial-institution interaction- Industrial projects, their, feasibility reports.
Interaction with industries.

References Books:

1. Research in Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
2. Practical Introduction o copyright. - Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furrness
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
14. Manual for the preparation of industrial feasibility studies

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920102
Specialization paper - III
Novel Drug Delivery System Part-I
Theory
(Six hours per week, 7 credits)

1. Recent Innovations in Conventional Dosage Forms – including site specific and time release modulation.

e.g.: Tablets: Osmotic, Colon target, Gastro-retentive, Buccal, and Sublingual.
Capsules: Modified release,
Semi-solids:
Parenterals:
Powders: Particle coating, Taste-masking,
Liquids:

2. Packaging components and its evaluation: factors affecting selection, Types and classification, Primary and secondary and regulatory aspects. Contribution in stability of the dosage forms.

Subject of Specialization paper - III
_ovel Drug Delivery System Part-I
Practical
(Six hours per week, 8 credits)

Laboratory examination including practical examination in general course illustrative of theory section in the syllabus.

References Books:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman** "The theory and Practice of Industrial Pharmacy" 3rd edition.
3. **Pharmaceutics** "The Science of Dosage form design" **by Aulton**
4. **Pharmaceutical dispensing** **by Husa**.
5. **Modern pharmaceutics** **by G. S. Banker**.
6. **Encyclopedia of pharmaceutical technology** Volumes: 1 to 19.
7. **Pharmaceutical dissolution testing** **by Banaker**.
8. **United States Pharmacopeia**.
9. **Drug stability (Principles and Practices)** **by Jens. T. Carstensen**.

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Master of Pharmacy
Semester – II
Paper code -2920202
Specialization paper - IV
Global Regulatory Requirements

Theory
(Six hours per week, 8 credits)

1. Validation of Pharmaceutical Processes, equipments/status, basic concept in analytical method development for dosage forms., Computer System validation, ERP and SAP systems.
2. Basics in Drug approval process with reference to: Orange book, Freedom of information, IIG, DMF, Historical aspects with Various phases of drug development and approval.
3. IND, NDA, ANDA , Concept of para I to IV, exclusivity: Content, format and Application.
4. Brief and comparative introduction to various regulatory agencies: USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.

Reference Book:

The guidance documents shall be procured from the website of the respective Government.