Gujarat Technological University

M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme Credits		Marking Scheme 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 a lied and Patent oriented Research) objective of Research
2. L iterature 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. Qualities studies, quantitative studies
    B. Simple data organization descriptive data analysis,
    C. L imitation & 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. Methology-subject, a aratus, 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. E rrata
    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 rivate 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 Furmess
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 -2920106
Specialization paper - III
Applied Pharmacotherapeutics - I
Theory
(Six hours per week, 7 credits)

Pathophysiology, Diagnosis & Pharmacotherapeutic management of following acute and chronic diseases and disorders

Basic Concepts of Pathophysiology and Pharmacotherapeutics

1. Cardiovascular

Hypertension, angina pectoris, congestive heart failure, myocardial infarction, cardiac arrhythmias.

2. Gastrointestinal

Peptic ulcer disease, Inflammatory Bowel diseases, hepatitis, cirrhosis, nausea and vomiting, constipation and diarrhea.

3. Respiratory

Chronic obstructive pulmonary disease, bronchial asthma, cystic fibrosis.

4. C_S

Epilepsy, Parkinsonism, schizophrenia, migraine, Alzheimer disease, Huntington's chorea, Spasticity), behavioral disorder-(Anxiety, Insomnia, Depression and Mania)

5. Endocrine

Endocrinal disorders including Diabetes mellitus, thyroid (hyperthyriodism and hypothyroidism), parathyroid diseases, hyperlipidemia and Adrenocortical dysfunction.

Specialization paper - III
Applied Pharmacotherapeutics - I
Practical
(Six hours per week, 8 credits)

• Each student has to undergo compulsory Hospital postings for understanding and gaining knowledge of Pathophysiology, Diagnosis & Pharmacotherapeutic management of various diseases and disorders.

• It is mandatory that each student has to maintain a record of at least 15 case studies based
on the theory topics

ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

References Books:

1 Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
2 Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
3 Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/ Glasgow/ Madras.
4 Robbins Pathologic Basis of Disease. Cartran, Kumar, Collins, W.B.Saunders. Latest edition.
5 Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
6 Pharmacotherapy: A Pathophysiologic approach – Joseph T. Dipiro et al. Appleton & Lange
7 Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)
8 Davidson's Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D. Boucher ELBS with Chu0rchill Living stone. Edinburgh. Latest Edition.
9 Avery's Drug Treatment, 4th End, 1997 Adis International Limited
10 Relevant review articles from recent medical and pharmaceutical literature.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920206
Specialization paper - IV
Clinical Research and Regulatory Affairs
Theory
(Six hours per week, 8 credits)

1. Introduction to Drug Discovery and drug Development
2. Clinical trials
Introduction and designing
Various phases of clinical trials
Post Marketing surveillance – methods
Principles of sampling
Inclusion and exclusion criteria
Methods of allocation and randomization
Informed consent process
Monitoring treatment outcome
Termination of trial
Safety monitoring in clinical trials
3 Documents in clinical study
Investigator Brochure (IB),
Protocol & Amendment in Protocol ,
Case Report Form (CRF),
Informed Consent Form (ICF) ,
Content of Clinical Trial Report
Essential Documents in Clinical Trial
4 Data Management in clinical Research
5 Ethical guidelines in clinical research
History
ICH-GCP & its Principles
Indian GCP (CDSCO Guidelines)
ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects
Schedule Y
6 Roles & Responsibility of various clinical trial personnel as per ICH GCP
Sponsor
Investigator
Monitor
Auditors
7 Institution Ethics Committee / Independent Ethics Committee
8 Quality Assurance in clinical Research
9 BA/BE studies: Introduction, Regulatory requirements and methodology

10 Clinical Trial Application in India
Import & Export of Drug in India
11 Investigational New Drug application (IND)
12 Abbreviated New Drug Application (ANDA)
13 New Drug Application (NDA)

ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

References Books:

1. Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004
2. Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002
3. Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002
4. Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006
5. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002
6. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication
7. Bert Spilker. Guide to Clinical Trials.
8. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009
9. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006
10. Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
11. Principals of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
12. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications.
13. Various Guidelines like:
_ ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996.
_ ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.
_ Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.
Schedule Y