Gujarat Technological University

M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. _o.	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 -2920104
Specialization paper - III
Modern Pharmaceutical Analysis
Theory
(Six hours per week, 7 credits)

1. Application of analytical methods to product obtained through genetic engineering , Amino acid sequence analysis, Tryptic maping, ion exchange amino acid analysis, isoelectric focusing etc.
2. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH
3. Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.
4. Applications of various analytical techniques in preformulation analysis and its importance.
5. Analysis of solid oral dosage form
6. Analysis of injectable dosage form
7. Compendial testing
8. Automated analysis
9. Compendial methods for evaluation of crude drug and herbal formulation
10. Quality control of radio pharmaceuticals and radio chemical method in analysis.
11. Analysis of cosmetics

Specialization paper - III
Modern Pharmaceutical Analysis
Practical
(Six hours per week, 8 credits)

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
2. Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
3. Determination of Total Chloride in Thiamine Chloride Hydrochloride.
4. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
5. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
6. Determination of related substances in Albendazole, Amiloride, Metronidazole,
7. Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol,

Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P.
Determination of active constituents in crude drugs. E.G. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
8. Quality Control tests for some herbal formulations.
9. Quality Control tests for some cosmetics.

References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs andPharmSci.Series,Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis
3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
6. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia,Vol. I and Vol. II - 1996.The Controller of Publications; New Delhi, Govt. of India,
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
11. Basic tests for pharmaceutical substances – WHO (1988)
12. Basic tests for pharmaceutical dosage forms – WHO (1991)
13. Phytochemical Methods by J.B.Haroborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920204
Specialization paper - IV
Regulatory Affairs and _ew Drug Application
Theory
(Six hours per week, 8 credits)

A) REGULATORY AFFAIRS

1. Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.
2. Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics- The Drugs & Cosmetic
Act 1940 & rules 1945 with amendments.
3. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
4. Quality safety and legislation for cosmetic and herbal products.
5. Aims, objects and salient features of following legislations governing Pharmaceutical Industry-
6. Pollution Control Act
7. Prevention of Food Adulteration Act 1954
8. Industrial Development & Regulation Act 1951
9. Consumer Protection Act
10. Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA
11. Drug Master File (Case Study-3 examples)
12. Material Safety Data Sheet (MSDS) preparation
13. Industrial Safety & Health Guide lines for filing in countries like US & EU
14. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US,
EU, Japan, ICH
15. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs,
Comparative picture of IP, USP, BP, EP&GP

B) Approval of _ew drugs:

Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content &
format of NDA, manufacturing control requirement of NDA.

References Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
th Ed., Vallabh Prakashan
4. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
5. P. Warayan, Intellectual Property Laws, Eastern Law House.
6 Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Bery, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci.
Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik
9. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Gahaziabad, Govt. of
India.
10. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
11. Pollution Control Act, 1974
12. Prevention of Food Adulteration Act 1954
13. Industrial Development & Regulation Act 1951
14. Consumer Protection Act 1986
15."WHO Expert Committee on specification on Pharmaceutical Preparation"34th report, Geneva,
World Health Organisation, 1996 (WHO Technical Report Series, No. 863
16. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and
Vol.2, WHO, (1999)
17. A.C. Cartwright and Brian Mathews,"International Pharmaceutical Registration" Taylor and Francis
Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication.