

Gujarat Technological University

M.Pharm

Pharmaceutical Management and Regulatory Affairs (Branch 16)

Proposed Teaching Scheme (W.E.F. January 2013)

Semester – II

Paper No	Subject Name	Teaching Scheme		Evaluation Scheme			
		Credit		Theory		Practical	
		Theory	Practical	External	Internal	External	Internal
2920001	Research Methodology	7	0	80	20	0	0
2921601	Regulatory Affairs-I	7	8	80	20	80	20
2921602	Pharm Management-II	8	0	80	20	0	0

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Semester – II

Subject Name: Research Methodology (Common to all Branches)

Subject Code: 2920001

Sr_No	Content	Hr.
1.	Research: Meaning, purpose, Types,(Educational, Clinical, Experimental, historicaldescriptive, Basic applied and Patent oriented Research) objective of research.	4
2.	Literature survey: Use of Library, books and journals-Medlines-Internet, Patent Search, andreprints of articles as a source for Literature survey.	3
3.	Selecting a problem and preparing Research proposals.	3
4.	Methods and tools use in research : a. Qualities studies, quantitative studies b. Simple data organization descriptive data analysis, c. Limitation & sources of Error d. Inquiries in form of Questionnaire, etc.	12
5.	Documentation: a. "How" of documentation b. Techniques of documentation c. Importance of documentation d. Use of computer packages in documentation.	11

6.	<p>The Research Report Paper writing/ thesis writing.</p> <p>Different parts of the Research paper</p> <ol style="list-style-type: none"> 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, 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 	12
7.	<p>Presentation (especially for oral presentation):</p> <p>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.</p>	6
8.	<p>Cost analysis of the project: cost incurred on raw materials, Procedure, instrumentations and clinical trials.</p>	3
9.	<p>Sources for procurement research grants: international agencies, Government and private bodies.</p>	3
10.	<p>Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries.</p>	3

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 Furness
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

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Subject Name: Regulatory Affairs-I(Theory)

Subject Code: 2921601

(Four hours per week, 4 Credits) Total: 60 hours

Sr_No	Content
1.	Origin, development, scope, objectives and nature of Pharmaceutical legislation in India. History and ethics of profession of Pharmacy.
2.	A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)
3.	The Narcotics Drugs and Psychotropic Substances Act.
4.	Medicinal and Toilet Preparations (Excise Duties) Act, 1955.
5.	The Pharmacy Act, 1948.
6.	The Drugs and Cosmetics Act, 1940 and Rules there under.
7.	Drugs (Price Control) Order in force.
8.	Introduction to Intellectual Property Rights; Copy Right Act, Trade Mark Act, Patent Act and Biodiversity Act, WTO, TRIPS and TRIMS.
9.	The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.
10.	Prevention of Cruelty to Animals Act.
11.	Schedule U requirements- Product development stage documentation, factory procedures - Standard operating procedures and standard test procedures

12.	Legal Environment of Business- Need for government regulations; financial regulations, SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws - Direct and Indirect.
13.	Indian Patent Law: Critical evaluation of development of Indian Patent law with necessary changes. Comparison with US and EP Patent Law.

Reference Books:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.

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Semester – II

Subject Name: Regulatory Affairs-I(Practical)

Subject Code: 2921501

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

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Proposed Teaching Scheme (W.E.F. January 2013)

Subject Name: Pharm Management-II(Theory)

Subject Code :2921602

Sr_No	Content
1.	Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities.
2.	Development of efficient work methods, quality control and management of R&D.
3.	Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.
4.	Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.
5.	Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.
6.	Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management. Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing

7.	Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment. Product management. E-PharmaMarketing.
8.	Product Planning: Selection of product, new product development and product differentiation, pricing, promotion - personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.
9.	Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.
10.	Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

Reference Books :

1. Management by Tripathi P. C. and Reddy P. N.; Tata McGraw Hill.
2. Business Organization and Management by Shukla M. C.; S. Chand and Company.
3. Business Organization and Management by Sherlakar S. A.; Himalaya.
4. Personnel Management by Filippo E. B.; McGraw Hill.
5. Marketing Management by Kotler Philip.; Prentice Hall of India.
6. Organizational Behavior by Rao and Narayan; Konark Publishers.
7. Personnel Management by Tripathi P. C.; S. Chand and Company.
8. Principle and Practice of Marketing in India by Memoria C. B.
9. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
10. Marketing Hand Book Vol. II , Marketing Management by Edwin - E Bobrow, Mark - D. Bobrow.
11. Production and Operations Management by S.N.Chary