Gujarat Technological University

M.Pharm

QUALITY ASSURANCE AND REGULATORY AFFAIRS (Branch 15)

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
2921501	Modern Pharmaceutical Analysis	7	8	80	20	80	20
2921502	GMP, GLP and Validation	8	0	80	20	0	0

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SEM II

Subject Name: REASEARCH METHODOLOGY(Common to all branches)

Subject Code: 2920001

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-Midlines-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. 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. 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
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
and clinical trials.
8. Sources for procurement research grants – international agencies, Government and private bodies.
9. 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

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SEM II

Subject Name: MODERN PHARM ACEUTICAL ANALYSIS (Specialization paper – III)

Subject Code: 2921501

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

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
And Pharm Sci.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)

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SEM II

Subject Name: GMP, GLP AND VALIDATION (Specialization paper – IV)

Subject Code: 2921502

Theory (Four hours per week, 8 Credits)

1. Concepts of Philosophy of QA, GMP, GLP .
2. Good Manufacturing Practices: |
a. Organization & Personnel, responsibilities, training, hygiene.
b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas and control of contamination.
c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).
d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.
e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.
g. Packaging and labelling control, Line clearance, reconciliation of labels, cartons and other packaging materials.
h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.
i. Finished product release, quality review, quality audits and batch release documents.
j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.
k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
m. Waste disposal, scrap disposal procedures and records.
3. Good Laboratory Practices.
4. Introduction to Pharmaceutical Validation:
Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master Plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.
5. Cleaning Validation: Cleaning of Equipment, Cleaning of Facilities.
6. Analytical Method Validation.

General principles of analytical method validation. Validation of following analytical Instruments

- HPLC
- Dissolution test apparatus
- U.V./Visible spectrophotometers

7. Process Validation

Prospective, concurrent, retrospective & revalidation, Process validation of following formulations

- Coated tablets
- Capsules
- Ointment/Creams
- Liquid Orals

8. Computer System Validation

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 135, 4th Ed., Marcel Dekker Inc., N.Y
3. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
4. P. P .Sharma “How to practice GMPs”, 3rd edition Vandana Publication.
5. P. P. Sharma “How to practice GLP” Vandana Publication.
6. S. Weinberg, “Good Laboratory Practice Regulation” Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
7. WHO’s “Drug” Bulletins.
8. Remingtons “Pharmaceutical Sciences”.
9. GMP practices for pharmaceutical-James Swarbrick.