C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: All Discipline

Semester: II

Name of Subject: Drug Regulatory Aspects & IPR (Theory)

Subject Code: PGMP201

TEACHING & EVALUATION SCHEME:-

Sr. No	Subject Code	Name of the Subject	Teaching Scheme (Hours/Week)				Evaluation Scheme										
							Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Marks	Hrs	Marks	Hrs		Marks	Hrs	Marks	Hrs		
1	PGMP201	Drug Regulatory Aspects & IPR	4	-	-	4	30	1.5	70	3	100	-	-	-	-	-	**100**

OBJECTIVES:

- To explore the regulatory provisions with respect to clinical trials, Investigational New Drug Application, New Drug Application, ANDA, market authorization of medicines, inspection of Pharmaceutical manufactures and product registration.
- To explore practical aspects repeated to patenting Students learning

PRE-REQUISITE:

- A course at UG level regarding regulatory aspects, law governing Pharmacy profession.
- A B. Pharm. Degree from any institution approved by AICTE or its equivalent.

COURSE OUTLINE:

Sr. No	COURSE CONTENTS	HRS
01	Drug Regulatory Aspects (India) Indian drug regulatory authorities, Central and State regulatory bodies (FDA), Drugs and Cosmetics Act and Rules with latest Amendments., New Drugs – Importation, Registration, development, clinical trials, BE NOC & B.E. studies, Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
02	**Approval of New 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.	10
03	**Drug Regulatory Aspects (International & highly regulated markets)** 1. US Requirements – (for Generic Drugs especially formulations). 2. CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, 0rphan Drugs, vanilla ANDA's, exhibit/pivotal batches, validation batches, various guidance issued by CDER, OGD, Orange Book (and patents), RLD (reference listed drug) for BE studies and the norms for US submission, bioequivalence and dissolution recommendations, packaging, stability studies and the product information leaflet, US FDA inspection (audits), pre-approval inspections and approvals. 3. European Union Requirements 4. All the aspects for European registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1). 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. **6.** GMP audits, role of quality assurance, product approvals and supplies.	15
04	Introduction to IPR & Patents – Development of IP law in India, IPR regime,	10

	introduction to IP laws in India, Introduction, patent legislation, Indian Patents Act 1970 and amendments, procedure for patent application, grant and opposition proceedings, patent licensing, patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP case laws. American & European patent system – Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system in Europe. Patent search, patent analysis & patent drafting. Allied Patents Related Issues: Exploitation of patent, abuse of patents, compulsory licensing, infringement analysis, drug-patent linkage.	
05	International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO. Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003. Introduction to geographical indication/trademark/copyright: filing procedures.	**10**
06	IPR and Pharmaceutical Research: Benefits of IPRs to improve the quality of research work Strategies for avoiding research duplications, infringements	**05**
	Total	**60**

LEARNING OUTCOMES:

- To get familiar with regulatory aspects related to Research & Development as well as manufacturing and marketing of Pharmaceutical Products

TEACHING & LEARNING METHODOLOGY:

- The course employs lectures and class discussions. It also includes presentation by students on a specific topic assigned to them by the faculty.

BOOKS RECOMMENDED:-

1. GMPs by Mehra
2. The Drugs and Cosmetic Act, 1940 by Vijay Mallik

3. How to Practice GMP by P.P.Sharma.
4. EMEA Publications and Guidance.
5. Orange Book, ICH guidelines, Indian Patents Act
6. Country specific Regulatory Guidelines (available from internet)
7. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
8. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
9. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
10. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
11. USPTO and WIPO Guidelines.
12. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.

E-RESOURCES:

1. www.mohfw.nic.in
2. www.usfda.gov
3. www.mhra.gov.uk
4. www.ich.org/cache/compo/363-272-1.html

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: All Discipline

Semester: II

Name of Subject: Research Methodology (Theory)

Subject Code: PGMP202

TEACHING & EVALUATION SCHEME:-

Sr. No	Subject Code	Name of the Subject	Teaching Scheme (Hours/Week)				Evaluation Scheme										
							Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Marks	Hrs	Marks	Hrs		Marks	Hrs	Marks	Hrs		
1	PGMP202	Research Methodology	4	-	-	4	30	1.5	70	3	100	-	-	-	-	-	**100**

OBJECTIVES:

- To make students familiar with various established methods used in pharmaceutical research.
- To familiar student with how to write thesis and Research publication
- To aware students about fund resources for research work

PREREQUISITES:-

- Basic knowledge in Bio pharmaceutics, pharmacokinetics & basics of drug delivery in body.
- Fundamental understanding of biostatistics
- B. Pharm. degree from any AICTE approved institution or its equivalent.

Detailed Syllabus (Theory)

Sr. No	COURSE CONTENTS	Hrs
1	**Basics of Research** Definition, objectives, motivation, types of research (Educational, Clinical, Experimental, and Historical descriptive, Basic applied and Patent oriented Research) and approaches: descriptive research, conceptual, theoretical, applied and experimental.	05
2	**Formation of Research Proposal** A. Research Process: To determine what type of research to be done, Plan of research work. B. Selection of research area, prioritization of research. C. Literature review: importance and methods, sources (Use of Library, books and journals-Medline-Internet, Patent, articles) D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints, steps, problems in scheduling, limitations.	06
3	**Industrial-institution interaction-** Industrial projects, their, feasibility reports. Interaction with industries.	04
4	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	12
5	**Cost analysis & Funding / Scholarship** Cost analysis of the project – cost incurred on raw materials- Procedure, instrumentations and clinical trials. Agencies (international agencies, Government and private bodies.) funding research in pharmaceutical sciences, Scholarship, types of scholarships in education.	07
6	**Documentation-** A. "How" of documentation	03

	B. Techniques of documentation C. Importance of documentation D. Use of computer packages in documentation.	
7	**Research Deliverables** a) **Various Forms of Publication**: Thesis, paper, research proposal. b) **Research Report Paper writing Thesis Writing/:** 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 c) **Presentation: Poster, proposal, and oral paper 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.	20
8	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, Bibliography, end note.	03

LEARNING OUTCOMES:

- The student will be able to understand the hierarchy of continue research by proper fundamental methodology and knowhow about research publication and resources for research grant.

TEACHING & LEARNING METHODOLOGY:

- Faculty member/s shall explain in a class room using black board and multimedia projector
- The course employs lectures and class discussions. It also includes presentation by students on a specific topic assigned to them by the faculty.

RECOMMONDED BOOKS:

1. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.
2. J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.
3. J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education", 7th Ed. Boston: McGraw-Hill.
4. G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. Medical Education, 37(4): 376-385.
5. Manual for evaluation of industrial projects-United Nations.
6. Manual for the preparation of industrial feasibility studies.
7. Protection of industrial Property rights- P. Das & Gokul Das.
8. Documentation – Genesis & Development 3792.
9. Thesis projects in Science & Engineering – Richard M. Davis.
10. Thesis & Assignment – Jonathan Anderson.
11. Writing a technical paper- Donald Menzel.
12. Effective Business Report Writing –Leland Brown.

13. Spelling for the millions- Edna Furmess.

14. Preparation for publication – King Edward Hospital Fund for London.

15. Information Technology – The Hindu speaks.

16. Presentation skills - Michael Hallon- Indian Society for Institute education.

17. Practical Introduction of copyright. - Gavin Mcfarlane.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutical Chemistry & Pharmaceutical Analysis

Discipline: Pharmaceutical Analysis

Semester: II

Name of Subject: Pharmaceutical Analysis-I (Theory)

(Specialization-III)

Subject Code: PGMP241

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Name of the Subject	Teaching Scheme (Hours/Week)				Evaluation Scheme									
							Theory					Practical				Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Marks	Hrs	Marks	Hrs		Marks	Hrs	Marks	Hrs		
1	PGMP241	Pharmaceutical Analysis-I	4	2	6	12	30	1.5	70	3	100	30	6	70	6	100	**200**

OBJECTIVES:-

- To make students familiar with evaluation of drugs and cosmetics by various methodologies in pharmacy.

PREREQUISITES:-

- B. Pharm. degree from any AICTE approved institution or its equivalent

COURSE OUTLINE:-

Sr. No	Course Contents	Hours
1	General method of analysis to determine the quality of raw materials used in cosmetic industry	3
2	Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows.	8
3	Quantitative estimation of following functional groups A. Hydroxyl B. Ester C. Amine D. aldehyde E. Carboxylic acid	8
4	Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation with case studies	8
5	Quality control of Radiopharmaceuticals	4
6	Solid state analysis of drug substance including a detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action, with case studie	7
7	Introduction to harmonization and ICH, brief about ICH Guidelines with special consideration of Q1 and Q2	9
8	Impurity profiling: use of LC-MS, LC-IR, LC-NMR. Case Studies: Impurity profiling, Isolation and Characterization	5
9	Stability indicating assay with case studies	4

10	Quality control test of containers (glass, plastics, paper) , labels, label adhesive, cartons	**4**
	Total	**60**

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutical Chemistry & Pharmaceutical Analysis

Discipline: Pharmaceutical Analysis

Semester: II

Name of Subject: Pharmaceutical Analysis-I (Theory)

(Specialization-III)

Subject Code: PGMP241

Detail syllabus (Practical)

1. Physical stability testing of dosage form
   - Solids – Tablets, Capsules, Powders & Granules
   - Emulsions and Suspensions
2. Photo stability study of drug and pharmaceuticals
3. QC test for herbal formulations and herbal ingredients
4. Determination of related substances in some API and formulations as per IP
5. Development and validation of simultaneous method for determination of two drugs by UV spectrometry
6. Quantitative estimation of following functional groups
   - A. Hydroxyl
   - B. Ester
   - C. Amine
   - D. Aldehyde
   - E. Carboxylic acid

LEARNING OUTCOMES:-

- At the end of the course, the student will be able to learn the basic techniques to evaluate drugs and cosmetics.

TEACHING & LEARNING METHODOLOGY: -

- Lectures by using black board and Power point Presentation, Visual Graphics, Practical demonstrations and Practical working.

BOOKS RECOMMENDED:-

1. WHO guidelines for quality control of herbal plant materials
2. ICH guidelines for impurity determination and stability study
3. ICH Q1 and Q2 guidelines
4. Indian pharmacopoeia volume 1 to 3
5. Drug stability : Principles and practices by Jens T. Carstensen
6. Pharmaceutical Dosage Form Design: Tablets- Vol I,II & III by Lachmann.
7. Theory and Practice of Industrial Pharmacy by Lachman.
8. Stability Testing of Drug Products by W.Grimm.
9. Martin Physical Pharmacy – IVth Edition.
10. Physical Pharmaceutics by Manavalam and Ramaswamy.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

E-RESOURCES:-

1. Research and Review articles from Elsevier journals
2. Research and Review articles from www.sciencedirect.com

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutical Chemistry & Pharmaceutical Analysis

Discipline: 1) Quality Assurance 2) Pharmaceutical Analysis

Semester: II

Name of Subject: Total Quality Management & Documentation (Theory)

(Specialization-IV)

Subject Code: PGMP232

Teaching & Evaluation Scheme:-

Sr. No	Subject Code	Name of the Subject	Teaching Scheme (Hours/Week)				Evaluation Scheme										
							Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Marks	Hrs	Marks	Hrs		Marks	Hrs	Marks	Hrs		
1	PGMP232	Total Quality Management & Documentation	4	2	-	6	30	1.5	70	3	100	-	-	-	-	-	**100**

OBJECTIVES:-

- To provide the student with understanding of the role of quality management and its implementation within the pharmaceutical industry.
- To introduce & build on the concept of quality in Pharmacy profession
- To expand the concept of quality at industrial level, including plant design / layout,environmental controls, etc.

PREREQUISITES:-

- A B. Pharm. degree from any AICTE approved institution or its equivalent.

COURSE OUTLINE:-

Sr. No	Course Contents	Hours
1	Quality: Concept of quality, nature of product quality, study of various approaches for quality like Deming', Juran, Crosby, Feigenbaum, Shikawa.	06
2	Concepts and Principles of TQM: • Customer • Never ending improvement • Control of business process • Upstream preventive management • Ongoing preventive action • Leadership and teamwork	07
3	Quality tools for TQM: Pie charts & bar graphs, histograms, run charts, pareto charts, force field analyzer, brain storming & affinity diagrams, tree diagrams, flow charts & modelling, scatter diagram and relations diagram.	06
4	Other approaches of quality management: ISO 9000 series.	04
5	In Process quality controls on various dosage forms: Tablets, capsules, liquid orals, injectables, aerosols, semisolids (sterile and nonsterile).	07
6	Pharmaceutical plant design: • Regulatory requirements of Pharma facilities with reference to cGMP • Design of Q.C. Laboratory • Design of effluent treatment plant	05
7	Material Safety Data Sheet (MSDS) preparation Standard institutes & certification agencies like ISI, BSS, ASTM, WHO, US-FDA, UK-MCA, TGA	09
08	Preparation of documents for New Drug Application (NDA) as per requirements of FDA and EUDRA guidelines. GMP requirements for FDA, PIC and ICH. Site Master Files, Out of specification. Stability studies as per ICH, EUDRA, FDA,	07

	Analytical Methodology	
09	Harmonization of regulatory requirements: Study of ICH common technical documents. Harmonization of Pharmacopoeial standards.	04
10	Quality by Design (QbD) and Process analytical technology (PAT) approach	05
	Total	60

LEARNING OUTCOMES:-

- At the end of the course, the student will be able to understand the quality management System, in process quality control that contributes to the control, quality and validity of a Product and/or service.
- The student will also acquire the information regarding the pharmaceutical plant and design operation.

TEACHING & LEARNING METHODOLOGY:-

- Faculty member/s shall explain in a class room using black board and multimedia projector.
- It also includes presentation by a students on a specific topic assigned to them by the Faculty.

RECOMMENDED BOOKS:

1. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
2. Total Quality Management- Guiding Principle for Application, J. P. Peker, ASTM manual series, Philadelphia.
3. Total Quality Management – The Key to Business Improvemetn, Champman & Hall, Londan.
4. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
5. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
6. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.

7. Project Management, Clifford F. Gray and Erik W., Larson Publisher: McGraw Hill Company.
8. Pharmaceutical Production facilities: Design and applications, Graham Cole, Publisher Taylor & Francis.
9. Production/Operations Management, El wood Bufa, Wiley Eastern Limited, New Delhi.
10. Planning and control, Samuel Eilon, Universal book corporation, Mumbai.
11. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu
12. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus.
13. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh
14. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin.

E-Resouces

1. www. mhra.gov.uk
2. www.tga.gov.au
3. www.usfda.org
4. www.astm.org
5. www.bsigroup.com