



# 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				Evaluation Scheme										
			(Hours/Week)				Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Mar ks	Hrs	Mar ks	Hrs		Mar ks	Hrs	Mar ks	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.



## C. U. SHAH UNIVERSITY

### 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	<b>Approval of New drugs:</b> 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	<b>Drug Regulatory Aspects (International &amp; highly regulated markets)</b> 1. US Requirements – (for Generic Drugs especially formulations). 2. CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan 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



## **C. U. SHAH UNIVERSITY**

	<p>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.</p> <p>American &amp; European patent system – Requirements for patenting, utility, novelty non-obviousness, patent specification &amp; claims, patent infringement and doctrine of equivalents, federal circuit and patent system in Europe.</p> <p>Patent search, patent analysis &amp; patent drafting.</p> <p>Allied Patents Related Issues: Exploitation of patent, abuse of patents, compulsory licensing, infringement analysis, drug-patent linkage.</p>	
<b>05</b>	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.	<b>10</b>
<b>06</b>	IPR and Pharmaceutical Research: Benefits of IPRs to improve the quality of research work Strategies for avoiding research duplications, infringements	<b>05</b>
	Total	<b>60</b>

### **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



## **C. U. SHAH UNIVERSITY**

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](http://www.mohfw.nic.in)
2. [www.usfda.gov](http://www.usfda.gov)
3. [www.mhra.gov.uk](http://www.mhra.gov.uk)
4. [www.ich.org/cache/compo/363-272-1.html](http://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				Evaluation Scheme										
			(Hours/Week)				Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Mar ks	Hrs	Mar ks	Hrs		Mar ks	Hrs	Mar ks	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 pharmaceuticals, pharmacokinetics & basics of drug delivery in body.
- Fundamental understanding of biostatistics
- B. Pharm. degree from any AICTE approved institution or its equivalent.



## C. U. SHAH UNIVERSITY

### Detailed Syllabus (Theory)

Sr. No	COURSE CONTENTS	Hrs
1	<b>Basics of Research</b> 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	<b>Formation of Research Proposal</b> 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	<b>Industrial-institution interaction-</b> Industrial projects, their, feasibility reports. Interaction with industries.	04
4	<b>Ethical issues in research</b> 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	<b>Cost analysis &amp; Funding / Scholarship</b> 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	<b>Documentation-</b> A. “How” of documentation	03



## C. U. SHAH UNIVERSITY

	B. Techniques of documentation C. Importance of documentation D. Use of computer packages in documentation.	
7	<b>Research Deliverables</b> a) <b>Various Forms of Publication:</b> Thesis, paper, research proposal. b) <b>Research Report Paper writing Thesis Writing/:</b> 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) <b>Presentation: Poster, proposal, and oral paper presentation.</b> Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fricht, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire.	20
8	<b>Plagiarism</b> Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, Bibliography, end note.	03



## **C. U. SHAH UNIVERSITY**

### **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.

### **RECOMMENDED 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.





## **C. U. SHAH UNIVERSITY**

13. Spelling for the millions- Edna Furness.
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:** Quality Assurance (Q.A)

**Semester: II**

**Name of Subject:** Modern Pharmaceutical Analysis (Theory)

(Specialization-III)

**Subject Code:** PGMP231

**Teaching & Evaluation Scheme:-**

Sr. No	Subject Code	Name of the Subject	Teaching Scheme				Evaluation Scheme										
			(Hours/Week)				Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Mar ks	Hrs	Mar ks	Hrs		Mar ks	Hrs	Mar ks	Hrs		
1	PGMP231	Modern Pharmaceutical Analysis	4	2	6	12	30	1.5	70	3	100	30	6	70	6	100	<b>200</b>

**OBJECTIVES:-**

- To make students familiar with various modern analytical methods used in pharmaceutical analysis

**PREREQUISITES:-**

- A student has basic knowledge of pharmaceutical analysis
- A B. Pharm. degree from any AICTE approved institution or its equivalent.



## C. U. SHAH UNIVERSITY

### COURSE OUTLINE:-

Sr. No	Course Content	Hours
1	Application of analytical methods to product obtained through genetic engineering , Amino acid sequence analysis, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc.	06
2	Regulatory requirement in pharmaceutical analysis – US-FDA, ICH	08
3	Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.	06
4	Applications of various analytical techniques in preformulation analysis and its importance.	04
5	Analysis of solid oral dosage form	04
6	Analysis of injectable dosage form	04
7	Compendial testing	03
8	Automated analysis	02
9	Compendial methods for evaluation of crude drug and herbal formulation	02
10	Quality control of radio pharmaceuticals and radio chemical method in analysis.	03
11	Analysis of cosmetics	03
12	Regulatory requirement for stability studies: A very brief introduction to FDA and WHO guidelines. Detail study of ICH guidelines (Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C).	05
13	Kinetic principles applied for stability evaluation and their applications in predicting shelf life and half life of pharmaceutical formulations. Importance of accelerated stability study.	08
14	Stability indicating assay.	02
	<b>Total</b>	<b>60</b>



# **C. U. SHAH UNIVERSITY**

**Faculty:** - Pharmaceutical Sciences

**Department:** Pharmaceutical Chemistry & Pharmaceutical Analysis

**Discipline:** Quality Assurance (Q.A)

**Semester: II**

**Name of Subject:** Modern Pharmaceutical Analysis (Practical)

(Specialization-III)

**Subject Code:** PGMP231P

## **Detailed Syllabus (Practical)**

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.
8. Determination of active constituents in crude drugs. E.G. Caffeine from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
9. Quality Control tests for some herbal formulations.
10. Quality Control tests for some cosmetics.

## **LEARNING OUTCOMES:-**

- At the end of the course, the student will be able to understand the modern analytical techniques, which is important for pharmaceutical analysis of various dosage form, crude drug and herbal formulation.



## **C. U. SHAH UNIVERSITY**

### **TEACHING & LEARNING METHODOLOGY:-**

- Faculty member/s shall explain in a class room using black board and multimedia projector.

### **RECOMMENDED 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).
15. Chemical Stability of Pharmaceuticals-A Handbook for Pharmacists, Kenneth Connors, John Wiley & Sons, Inc.
16. Stability testing of drug Products by W.Grimm.



## **C. U. SHAH UNIVERSITY**

17. Stability of Drugs and dosage form by Yoshioka and stella.

### **E-RESOURCES:-**

1. [www.fda.gov/downloads/Drugs/Guidances/ucm073517.pdf](http://www.fda.gov/downloads/Drugs/Guidances/ucm073517.pdf)
2. [www.fda.gov/downloads/Drugs/.../Guidances/ucm073507.pdf](http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073507.pdf)
3. [www.ipapharma.org/events/stability/Milind%20Joshi.pdf](http://www.ipapharma.org/events/stability/Milind%20Joshi.pdf)
4. [apps.who.int/prequal/.../pq.../1-2\\_RegulatoryRequirements.ppt](http://apps.who.int/prequal/.../pq.../1-2_RegulatoryRequirements.ppt)
5. [www.ich.org/fileadmin/.../ICH.../Guidelines/.../Q1E\\_Guideline.pdf](http://www.ich.org/fileadmin/.../ICH.../Guidelines/.../Q1E_Guideline.pdf)



# 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				Evaluation Scheme										
			(Hours/Week)				Theory					Practical					Total
			T	S	P	Total	Sessional Exam		University Exam		Total	Sessional Exam		University Exam		Total	
							Mar ks	Hrs	Mar ks	Hrs		Mar ks	Hrs	Mar ks	Hrs		
1	PGMP232	Total Quality Management & Documentation	4	2	-	6	30	1.5	70	3	100	-	-	-	-	-	<b>100</b>

**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.



## C. U. SHAH UNIVERSITY

### 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: <ul style="list-style-type: none"><li>• Customer</li><li>• Never ending improvement</li><li>• Control of business process</li><li>• Upstream preventive management</li><li>• Ongoing preventive action</li><li>• Leadership and teamwork</li></ul>	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: <ul style="list-style-type: none"><li>• Regulatory requirements of Pharma facilities with reference to cGMP</li><li>• Design of Q.C. Laboratory</li><li>• Design of effluent treatment plant</li></ul>	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





## **C. U. SHAH UNIVERSITY**

	Analytical Methodology	
<b>09</b>	Harmonization of regulatory requirements: Study of ICH common technical documents. Harmonization of Pharmacopoeial standards.	04
<b>10</b>	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 Improvemtn, Champman & Hall, London.
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.



## **C. U. SHAH UNIVERSITY**

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](http://www.mhra.gov.uk)
2. [www.tga.gov.au](http://www.tga.gov.au)
3. [www.usfda.org](http://www.usfda.org)
4. [www.astm.org](http://www.astm.org)
5. [www.bsigroup.com](http://www.bsigroup.com)