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 B. Techniques of documentation	03

	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: Pharmaceutics & Pharmaceutical Technology

Discipline: 1) Pharmaceutics 2) Pharmaceutical Technology

Semester: II

Name of Subject: Advance Drug Delivery-I (Theory)

(Specialization-III)

Subject Code: PGMP211

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	PGMP211	Advance Drug Delivery-I	4	2	6	12	30	1.5	70	3	100	30	6	70	6	100	**200**

OBJECTIVES:

- To get acquainted with Advancement in novel drug delivery systems, in terms of its formulation strategies, evaluation parameters and application.

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.

COURSE OUTLINE:

Sr. No	COURSE CONTENTS	HOURS
1	**Oral sustained release Drug Delivery Systems (DDS):** Physico chemical and Biological factors influencing design, dissolution controlled systems, Diffusion controlled systems, Bioerodible systems, Osmotically controlled systems, Ion Exchange systems. Gastro Retentive DDS, Advancement in capsule drug delivery,	08
2	**Polymers in drug delivery:** Polymer classifications, biodegradable and non biodegradable polymers and their applications in controlled release.	05
3	**Mucoadhesive Drug Delivery Systems:** Physiology of mucosa, mechanism of transmucosal permeation. Delivery through Gastro intestinal, buccal, rectal and vaginal routes, (It's formulation strategies & evaluation)	08
4	**Transdermal Drug Delivery Systems:** Fundamental of skin permeation, Approach for development, kinetic evaluation, formulation design & optimization, Advancement in TDDS	06
5	**Implants and Inserts:** Introduction, Reaction of Host to Implant, Reaction of Implant to Host, subcutaneous Implants, Intra muscular implants, Intra ocular implants, Intra vaginal Inserts, Intra uterine implants	03
6	**Novel ocular drug delivery systems**: Ocular therapeutics and constraints to effective delivery, formulation considerations to improve the ocular bioavailability, ocular inserts including insoluble and soluble inserts, non-corneal routes and their use for systemic drug delivery.	06
7	**Miscellaneous sustained Drug Delivery Systems:** Pulsatile Drug Delivery Systems, patented technology (Ring cap Technology, Liquid sustained release systems (Sol to gel system) etc.	05

8	**Package development:** Package types for different dosage forms, packaging materials, labelling, preformulation screening of package components.	07
9	**Systematic Optimization of Pharmaceutical Formulation**	12
	Total	60

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutics & Pharmaceutical Technology

Discipline: 1) Pharmaceutics 2) Pharmaceutical Technology

Semester: II

Name of Subject: Advance Drug Delivery-I (Practical)

(Specialization-III)

Subject Code: PGMP211P

Detailed Syllabus (Practical): To illustrate the topics included under theory

LEARNING OUTCOMES:

- With help of gained knowledge students can handle research project in novel drug delivery systems in his/her dissertation work & in pharmaceutical industry.
- Student can be able to optimize pharmaceutical formulation using Design of Experiments

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.
- Presentation on a case related to the course.

BOOKS RECOMMENDED:-

1. Encyclopedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
2. Theory and Practice of Industrial Pharmacy, L. Lachman, Vargish Publication, Bombay.
3. Modern Pharmaceutics, G.S. Banker and C.T. Rhodes, Marcel Dekker, Inc., New York.

4. Controlled Drug Delivery : J. R. Robinson and V. H. Lee, Marcel Dekker, Inc., New York.

5. Novel Drug Delivery Systems, Y.W. Chien, Marcel Dekker, Inc., New York.

6. Progress in Controlled and Novel Delivery Systems, edited by N.K. Jain, CBS Publishers & Distributors, New Delhi.

7. Targeted & Controlled Drug Delivery, S. P. Vyas and R. K. Khar, CBS Publishers & Distributors, New Delhi.

8. Advances in Controlled and Novel Drug Delivery, Edited by N.K. Jain, CBS Publishers & Distributors, New Delhi

9. Pharmaceutical Dosage Forms: Disperse system, Vol. I, II &III, Lierberman H. A. and Leon Lachman, Marcel Dekker, New York

10. Handbook of Pharmaceutical Controlled Release Technology, Donald L. Wise, Marcel Dekker, USA.

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutics & Pharmaceutical Technology

Discipline: Pharmaceutics

Semester: II

Name of Subject: **Quality Assurance, GMP & Process Validation** (Theory)

(Specialization-IV)

Subject Code: PGMP212

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	PGMP212	Quality Assurance, GMP & Process Validation	4	2	-	06	30	1.5	70	3	100	-	-	-	-	-	**100**

OBJECTIVE:

Students get acquainted with understanding of various aspects of Quality Assurance System, Good Manufacturing Practices and Process Validation, these will help them in pharmaceutical industry.

PREREQUISITES:-

- Fundamental understanding of Industry Pharmacy aspects
- B. Pharm. degree from any AICTE approved institution or its equivalent.

OUTLINE OF THE COURSE:

Sr. No	COURSE CONTENTS	HOURS
01	**Quality Assurance:** · Role of raw material testing, finished product testing, in process quality control in assuring quality of drug products · Quality audit & quality circle in quality assurance · Application of Process Analytical Technology (PAT) in quality assurance	10
02	**Good Manufacturing Practices (GMP) :** · Role & objective of GMP, · Provisions of GMP with respect to followings General provisions related to finished pharmaceuticals Building & facilities Equipments Personal Containers & closures Production & process control Packaging & labeling controls Records & reports	30
03	**Process Validation** · Regulatory basis, Terminology: validation, qualification, calibration · Prospective process validation · Retrospective validation · Validation of sterilization processes (Heat & Filtration) · Validation of tablets & capsules manufacturing processes · Qualification of water systems · Qualification of Air-Handling systems	15

	· Qualification of Equipments · Qualification of Facility · Validation & verification of cleaning process · Computer system validation	
04	Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M.	**05**

LEARNING OUTCOMES:

The basic understanding acquired by the student at the end of the course shall help him/her to appreciate the Quality Assurance System & Validation aspects of a Pharmaceutical Industry.

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.

BOOKS RECOMMENDED:-

1. How to practice GMPs; P.P.Sharma, 5th Edition, Vandhana Publications, New Delhi.

2. Pharmaceutical process validation, Bernard T. L. and Robert A. Nash, Volumes 23, Marcel Decker.

3. Good Manufacturing Practice for pharmaceuticals, Sidney H. Willing, Mercel Decker Inc.

4. Validation of Pharmaceutical Process, James Agalloco, 3rd Edition, Infroma Healthcare USA

5. Validation of Pharmaceutical Processes, Sterile Products, F.J.Carleton, Marcel Dekker Inc.

6. Guidelines on cGMP & Quality of Pharmaceutical Products, S. Iyer, D.K. Publication, Mumbai.

7. Validation in Pharmaceutical Industry (Concept, Approches & Guidelines), P.P. Sharma, Vandhana Publications, New Delhi