C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: All Discipline

Semester: I

Name of Subject: Modern Analytical Techniques (Theory)

Subject Code: PGMP101

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	PGMP101	Modern Analytical Techniques	4	-	6	10	30	1.5	70	3	100	30	6	70	6	100	**200**

OBJECTIVES:-

- To make students familiar with the principles of modern analytical techniques and its application in pharmacy
- To give training in use of the technique & its applications in day to day practice
- To build on the basics learned at UG level & give latest advances in the area
- To give more stress on application based knowledge than instrumentation based one
- To give hands on training on use of as many different sophisticated instruments as possible

PREREQUISITES:-

- Minimum two UG level courses in Pharmaceutical analysis
- A B. Pharm. Degree from any AICTE approved institution or its equivalent

COURSE OUTLINE:-

Sr. No.	Course Content	Hours
1	**UV – Visible spectroscopy:** Theory, chromophores and their interaction with EMR, solvent effects, instrumentation (components and their function) & applications including multi-component assay and derivative spectra. Woodward-Fieser and Fieser-Kuhn rules for calculating absorbance maximum and interpretation of spectra.	06
2	**Infrared spectroscopy:** Introduction, basic principles, instrumentation (components and their function), sampling techniques, interpretation of spectra and applications. Theory and applications of FTIR,ATR and NIR.	06
3	**Nuclear Magnetic Resonance Spectroscopy:** Fundamental principle and theory of proton NMR, instrumentation, solvents, chemical shift, spin-spin coupling, coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT- NMR, 2D-NMR, applications in pharmacy and interpretation of spectra. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling and its structural applications.	10
4	**Mass Spectroscopy:** Basic principle and instrumentation, ion formation and type, fragmentation process and fragmentation pattern, chemical ionization mass spectroscopy (CIMS), field ionization MS (FIMS), Fast atom bombardment MS (FAB-MS), matrix assisted laser desorption/ ionization MS (MALDI-MS), Interpretation of spectra and application in pharmacy, Surface Ionization MS(SIMS).	08
5	**Optical Rotary Dispersion:** Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.	03
6	**Thermal Methods of Analysis** : Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravitry (TG), Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	03

7	**Chromatographic techniques:** Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation. Principles, elution techniques, instrumentation, derivatization and application of GC, HPLC, HPTLC. Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, Size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC),UPLC, GC-MS, short column chromatography, flash chromatography, medium pressure LC and LC-MS.	18
8	**Radio analytical techniques used in pharmaceuticals:** Isotopic dilution methods, Radioimmunoassay, ELISA etc.	02
9	**Electrophoresis:** Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.	02
10	Application of Transmittance Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM).	02
Total		60

Faculty: - Pharmaceutical Sciences

Department: All Discipline

Semester: I

Name of Subject: Modern Analytical Techniques (Practical)

Subject Code: PGMP101P

Module-1: UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures and isosbestic point in case of mixtures.

Module-2: Effect of solvents and pH on UV spectrum of drugs

Module-3: Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g. Vitamins, Oral antidiabetics, NSAIDs, Antimicrobials, Antihistamines, Antihypertensive etc.

Module-4: Experiments based on the application of derivative spectroscopy.

Module-5: Experiments based on HPLC (Isocratic and Gradient elution) techniques.

Module-6: Interpretation of drugs by IR spectra

Module-7: Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of few compounds

Module-8: Separation of protein drug substances by electrophoresis

Module-9: Use of fluorimeter for analysis of Pharmacopoieal compounds.

Module-10: Experiments of Chromatography. (a) Thin Layer Chromatography, (b) Paper Chromatography.

Module-11: Any other relevant experiments based on theory.

LEARNING OUTCOMES:-

- At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

TEACHING & LEARNING METHODOLOGY:-

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

BOOKS RECOMMENDED:-

1. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers Delhi
2. Chromatographic Analysis of Pharmaceuticals, A. John, Adamovics, Cytogan Corporation, Princeton, NJ.
3. Clarke's Analysis of Drugs and Poisons, A.C.Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press.
4. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
5. Handbook of Instrumental techniques for analytical chemistry, Frank Settle,1st edition, Pearson education, Singapore.
6. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
7. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, 2nd Edition, P. D. Sethi, CBS Publishers and Distributers, New Delhi.
8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
9. Instrumental Methods of Chemical Analysis, B.K. Sharma, Goel Publication House, Meerut, India.
10. Instrumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill Book Co, NY.
11. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
12. Modern Methods of Pharmaceutical Analysis, Vol 1, 2, RE Schirmer, Franklin Book Co, PA.

13. NMR spectroscopy (Basic Principles, concepts and application in Chemistry) Herald Gunther (John Wiley and Sons), NY..
14. Organic Spectroscopy – William Kemp, 3rd Edition.
15. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical formulations (VBS Publishers, Delhi).
16. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
17. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th edition.
18. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
19. Remington's Pharmaceutical Sciences, J. P. Remington, Mack Pub. Co., Pennsylvania.
20. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
21. Spectroscopic identification of organic compounds. John Dyer, Willy, NY.
22. Spectroscopy of Organic Compounds by P. S. Kalsi.
23. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
24. Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.
25. United States Pharmacopoeia-27(NF-22), 2004, United State of Pharmacoppeal convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
26. British Pharmacopoeia, 2004, The British Pharmacopoeia commission office, Market Tower, Nine Elms Lane, London.
27. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission, Sector-23, Raj Nagar, Ghaziabad.

E-RESOURCES:-

1. www.**jasco**inc.com/
2. www.ssi.**shimadzu**.com
3. www.perkinelmer.com
4. www.phenomenex.com

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: All Discipline

Semester: I

Name of Subject: Biostatistics (Theory)

Subject Code: PGMP102

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	PGMP102	Biostatistics	2	-	-	02	15	1	35	2	50	-	-	-	-	-	**50**

OBJECTIVES:

- To explain students with various Statistical Techniques used to draw conclusions in Experimental Research.
- To emphasize the use of these Techniques to address the problems and issues arising in the discipline of Pharmacy and to find their solutions using Statistical Software.

PREREQUISITES:-

- 10 + 2 level mathematics knowledge.
- B, Pharm. Degree from any institution approved by AICTE or its equivalent.

COURSE OUTLINE:

Sr. No	COURSE CONTENTS	HRS
01	**Introduction:** Relevance and the scope of Statistics. Difference between 'Descriptive' and 'Inferential' Statistics; Relationship between them	02
02	**Test of hypothesis** Concepts of hypothesis testing and types of errors. Point and interval estimation including fiducial limits, t-test, Chi square tests, f-test, Z-test. **Non parametric test lik:** Sign test, Mann-Whitney U test, Wilcoxon sign rank test, Kruskal wallis test	11
03	**Correlation and regression:** Introduction and Theory, different method of correlation (graphical method, Person's product moment, correlation coefficients, Spearman rank correlation. **Regression**: Regression line, Determination of Regression coefficients, Multiple regression analysis	07
04	**ANOVA** Introduction, One Way ANOVA, Two way ANOVA and it's statistical inferences	05
05	**Experimental design in clinical trials;** Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies	04
06	**Introduction to common software**	01
	Total	30

LEARNING OUTCOMES:

- Students will able to identify, analyze and solve problems related to biostatistics using statistical software.

- Students can apply biostatics application in order to understand various pharmaceutical process variables, understand significance effect on parameters in clinical trials

TEACHING & LEARNING METHODOLOGY:

- Lectures will be taken in class room with the aid of multi-media presentations / black board or mix of both.
- Assignments based on the course content will be given at the end of the topic.

BOOKS RECOMMENDED:-

1. Stanford Bolton, Charles Bon (2004), Pharmaceutical Statistics, Practical and Clinical Applications (Fourth rev. ed) Marcel Dekker, Inc
2. Dowdy, S., and Wearden, S. (1991), Statistics for Research (2nd ed.), New York: John Wiley.
3. Freund, R. J., and Wilson, W. J. (1997), Statistical Methods (rev. ed.), San Diego, CA: Academic Press
4. Miller, R. G., Efron, B., Brown, B. W., and Moses, L. E. (eds.) (1980), Biostatistics Casebook, New York: John Wiley.
5. Steel, R. G. D., and Torrie, J. H. (1980), Principles and Procedures of Statistics: A Biometrical Approach (2nd ed.), New York: McGraw-Hill.
6. Woolson, R. F. (1987), Statistical Methods for the Analysis of Biomedical Data, New York: John Wiley.
7. Wackerly DD, Mendenhall W, Scheaffer RL. Mathematical Statistics with Applications, 7th edition, 2008, Duxbury Press, USA
8. Piantadosi S. (2005), Clinical Trials a Methodological Perspective, 2nd edition. John Wiley & Sons.
9. Senn S. Cross-over trials in clinical research, 2nd edition. Wiley, 2002.
10. Jennison C. and B.W. Turnbull. Group sequential methods with applications to clinical trials. Chapman & Hall, 1999.

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutical Chemistry & Pharmaceutical Analysis

Discipline: Quality Assurance (Q.A)

Semester: I

Name of Subject: Method of Drug Evaluation & Clinical Research (Theory)

(Specialization-I)

Subject Code: PGMP131

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	PGMP131	Method of Drug Evaluation & Clinical Research	4	2	6	12	30	1.5	70	3	100	30	1.5	70	3	100	**200**

OBJECTIVES:-

- To train students about various biological evaluation methods & the significance of such tests
- To impart knowledge about official / non-official methods of evaluation for a wide range of pharmaceutical dosage forms
- To give wide exposure to students in the area of New Chemical Entity pre-clinical evaluations & related areas
- To give them training in carrying out some of these techniques in the laboratory

PREREQUISITES:-

- At least two courses each in Pharmaceutics & biology / microbiology or related biological subjects at UG level
- A B. Pharm. degree from any institution approved by AICTE or its equivalen

COURSE OUTLINE:-

Sr. No	Course Content	Hours
1	Biological Standardization: General Principles, Scope & limitations of Bioassays Bio- assays of some Official Drugs.	04
2	Sterility Tests: Methodology & Interpretation.	04
3	Pyrogen - chemistry and properties of bacterial pyrogens and endotoxins.Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests.	05
4	Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.	05
5	Microbiological Limit Tests, Tests for effectiveness of antimicrobial preservatives.	06
6	Radio immunoassay: General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.	04
7	Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 &ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity	07

	and mutagenicity.	
8	Clinical Research— a. Clinical Research Protocols, objective and protocol design. b. Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study. c. Good Clinical Practices.	10
9	**Bioavailability:-** Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.	07
10	**Pharmacokinetics:-** Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.	08

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutical Chemistry & Pharmaceutical Analysis

Discipline: Quality Assurance (Q.A)

Semester: I

Name of Subject: Method of Drug Evaluation & Clinical Research (Practical)

(Specialization-I)

Subject Code: PGMP131P

Detailed syllabus (Practical)

1. Bio-analytical method development and its validation.
2. Analysis of biological fluids.
3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. Any other relevant exercises based on theory.

LEARNING OUTCOMES:-

- At the end of the course, the student will be able to learn the basic techniques to evaluate drugs using various animal models for different pathological conditions.

TEACHING & LEARNING METHODOLOGY:-

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

BOOKS RECOMMENDED:-

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia

4. Bengt Ljunggvist and Berit Davis “Microbiological Risk Assessment in Pharm. Clean rooms”. Harwood International Publishing.
5. Richard Prince, “Microbiology in Pharmaceutical Manufacturing”. Davis Harwood International Publishing.
6. Akers, “Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing,” 2nd Edition (Marcel Dekker).
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi..
8. Mark C. Rogge and David R Taft, “Prclinical Drug Development”, Drugs and Pharm. Sci. Series, Vol. 152, Marcel Dekker Inc., N.Y.
9. Donald Monkhouse, Charles Carney and JimClark, “Drug Products For Clinical Trials”. 2nd Ed. v Drugs and Pharm. Sci. Series, Vol. 147, 2nd Ed., Marcel Dekker Inc., N.Y.
10. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
11. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. S Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
12. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
13. Notari.-Biopharmaceutics and Pharmacokinetics-An introduction.
14. John Wagner- Pharmacokinetics for Pharmaceutical scientist.
15. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.

E-RESOURCES:-

1. www.**fda**.gov/science**research**/.../running**clinicaltrials**/..
2. www.**fda**.gov/regulatoryinformation/**guidance**s/ucm122049.htm
3. www.ncbi.nlm.nih.gov/mesh/68004353
4. *www.bionas-discovery.com › ... › B2500 › Pre-clinical Drug Evaluatio*
5. *www.reference.md/files/D004/mD004353.html*

C. U. SHAH UNIVERSITY

Faculty: - Pharmaceutical Sciences

Department: Pharmaceutical Chemistry & Pharmaceutical Analysis

Discipline: 1) Quality Assurance (Q.A) 2) Pharmaceutical Analysis

Semester: I

Name of Subject: Quality Assurance Technique (GMP/GLP) (Theory)

(Specialization-II)

Subject Code: PGMP132

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	PGMP132	Quality Assurance Technique (GMP/GLP)	4	2	-	6	30	1.5	70	3	100	-	-	-	-	-	**100**

OBJECTIVES:-

- To make students familiar with good manufacturing processes and good laboratory practices.
- To make students familiar with quality assurance prospective
- To teach this concept with respect to manufacturing activities & related areas, management of all store requirement & related matters.

PREREQUISITES:-

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

COURSE OUTLINE:

Sr. No	Course Content	Hours
1	Concepts and Philosophy of QA, Role of quality audit & quality circle in quality assurance Quality by Design and Quality risk management (ICH Q8&Q9). Pharmaceutical Quality System (ICH Q10).	06
2	Concept of Good Manufacturing Practices Organization & Personnel, responsibilities, training, hygiene.	02
3	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.	02
4	Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).	02
5	Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.	04
6	Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.	04
7	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.	08
8	Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials.	02
9	Quality control Laboratory: Responsibilities. Routine controls instruments,	08

	reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.	
10	Finished product release, quality review, quality audits and batch release documents.	02
11	Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.	02
12	Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.	03
13	Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.	02
14	Waste disposal, scrap disposal procedures and records.	02
15	Good Laboratory Practices.	05
16	WHO certification.	02
17	Testing of Packaging materials.	02
18	Specifications for materials, intermediates and finished product.	02
	Total	60

LEARNING OUTCOMES:-

- At the end of the course, the student will be able to study worldwide accepted manufacturing processes, good laboratory practices and basic of quality assurance.

TEACHING & LEARNING METHODOLOGY:-

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

BOOKS RECOMMENDED:-

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and S 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.
10. Quality Assurance of Pharmaceuticals, Volume I& II, (A Compendium guidelines & Related Materials), Pharmabook Syndicate, WHO, Geneva.
11. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune.
12. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
13. Good laboratory Practice, Jurg Seiler, Springer New York.
14. Good Laboratory Practice and Regulatory Issues, P. V. Mohanan, Educational book centre, Mumbai

E-RESOURCES:-

1. www.**ich**.org/products/guidelines/**quality**.html
2. www.werum.de/en/gb/filedown/filedowndb.jsp?.../txt/...A..
3. *indiaglp.gov.in/*
4. www.fda.gov/drugs/.../**manufacturing**/ucm169105.htm
5. *www.who.int/medicines/areas/quality_safety/quality.../production/*