M. PHARM

SPECIALIZATION: QUALITY ASSURANCE

FIRST YEAR

Subject Code	Subject	Teaching Scheme			Marking System			
		Theory (Hrs)	Practical (Hrs)	Total Hours	Theory		Practical	
					External	Internal	External	Internal
08200101	Modern analytical technique (Common For all Streams)	3	4	7	100	50	100	50
08205101	Research Methodology and Regulatory Affairs & NDA	4	-	4	100	50	-	-
08205102	Pharmaceutical Evaluation Techniques	3	6	9	100	50	100	50
08205103	GMP & Validation	3	6	9	100	50	100	50
		Total Hours		29				

SUJECT NAME: MODERN ANALYTICAL TECHNIQUES
SUBJECT CODE: 08200101

Objective of the course:

To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy

Students learning outcomes/objectives:

A] Knowledge:

1) Students will able to analysis of various drugs in single and combination dosage forms
2) 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
3) Illuminate relevance & significance of Advance analytical techniques to Pharmaceutical Sciences.
4) Understand the basic principles of chromatographic, spectroscopic and scattering methods.
5) Apply spectroscopic methods for analysis of Raw materials and Formulation.
6) Develop an in-depth knowledge and critical awareness of the application of modern analytical methods.
7) Understand and apply different spectroscopic and separation on raw materials.
8) Explain types, instrumentation and applications of spectroscopic, chromatographic and separation techniques
9) Define and compare the terms used in spectroscopic methods like UV-VIS Spectroscopy, IR Spectroscopy, NMR andMass Spectroscopy.
10) Understand & apply the theory and operational principles of UV-VIS Spectroscopy, IR Spectroscopy etc .
11) Understand the basic concepts and applications of Mass Spectroscopy.
12) Elucidate structure of organic compounds by various spectroscopic methods.

B. Skills:

1. Clarify and understand the correct use of laboratory instruments like UV-Visbilespectrophotometer,High Performance Liquid Chromatography , Flame Photometer with calibration of various instruments used in pharmaceutical analysis laboratory together with safety measures to be followed.
2. Develop practical hand in analytical methods by estimation of analyte concentration in pure form and in formulation with thorough understanding of principle and procedures used in different analytical techniques.
3. Develop UV and HPLC method for simultaneous estimation of Drugs
4. Various advanced analytical instrumental techniques for identification, characterization and quantification of drugs using IR, HPLC and TLC

THEORY (3 HOURS/WEEK)

Chapter No.	Topics	Hours Allotted
1	**UV-VISIBLE SPECTROSCOPY** Theory of UV-Spectroscopy, absorption law and limitations, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward–Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.	06
2	**INFRARED SPECTROPHOTOMETRY:** Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near Infrared Spectroscopy (NIR) -theory and applications,.	06
3	**NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:** Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing thevalue of coupling constant, spin-spin decoupling, proton exchange reactions, simplificationof complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation ofspectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.	08
4	**MASS SPECTROMETRY** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Tandem Mass Instruments, Interpretation of spectra and Applications of Mass spectrometry.	08
5	**ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:** Principle, instrumentation, interferences and applications in Pharmacy.	04

6	**X-RAY DIFFRACTION METHODS:** Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications	**04**
7	**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**
8	**THERMAL METHODS OF ANALYSIS:** Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC). And Thermo Mechanical Analysis (TMA).	**04**
9	**CHROMATOGRAPHIC TECHNIQUES:** a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation. b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC. c)Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, and chiral chromatography, super fluid chromatography (SFC), GC-MS, UPLC and LC-MS-stability studies and its applications.	**15**
10	**ELECTROPHORESIS:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing	**03**
11	**RADIO IMMUNO ASSAY:** Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related ImmunoAssay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT	**03**

12	**REFERENCE STANDARDS** Source, preparation, characterization, usage, storage , records and Concept of Working standard.	**02**
13	**ELECTRON MICROSCOPY:** Introduction to Scanning Electron Microscopy and Travelling Electron Microscopy.	**02**
14	**PREFORMULATION:** (a) Physical, Chemical and Pharmaceutical factors influencing formulation (b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties (c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form (d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study. (e) Drug-excipient compatibility study (f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents). (g) Preformulation studies of Biotechnological derived products and reference guidelines.	**07**

PRACTICAL (4 HOURS/WEEK)

1. Study of effect of solvent on wavelength maxima of drugs.

2. Find Beer's law limit of drugs in suitable solvent(linearity-range).

3. Multicomponent analysis by UV-Spectrophotometry

   a) Absorbance corrected for interference method

   b) Simultaneous equation method

   c) Absorbance ratio method

   d) Area under curve method

   e) First derivative spectrophotometric method

4. Assay of drugs official in various pharmacopoeias (Any five). This should cover UV spectrophotometry, HPLC methods.

5. Interpretation of some unknown intermediates and drugs.

a. Interpretation of UV spectra (At least one exercise),
b. Interpretation of IR spectra (At least two exercise),
c. Interpretation of NMRspectra (At least two exercise) and
d. Interpretation of Mass spectra(At least two exercise)
e. Structure elucidation based on UV, IR, NMR & MS.(At least five exercises)

[Note: For interpretation NMR and Mass spectral data, the spectra can be obtained from available literature]

6. Experiment on Flame Photometer.

7. Experiment on Fluorimetry.

Reference Books:

1. M. Orchin and H.H. Jaffe – Theory and applications of Ultraviole spectroscopy. (John Wiley and Sons. N.Y).
2. Silverstein, Basseler, Morril- Spectrometric identification of organic compounds (John Wiley and Sons. N.Y).
3. Willard, Merritt, Dean – Instrumental methods of analysis (CBS Publishers and Distributors, Delhi).
4. J.R. Dyer – Application of absorption Spectroscopy of Organic Compounds (Prentice Hall,London).
5. C.N.R. Rao – Chemical Applications of Infrared spectroscopy. (Academic Press, N.Y.).
6. L.M. Jackmann and B.D. Sternhell – Application of NMR spectroscopy in organic chemistry(Pergamon Press, London.).
7. F.W. McLafferty and F. Turecek- Interpretation of Mass Spectra.
8. R.J. Hamilton and P. A. Sewell- Introduction to High Performance Liquid Chromatography.(Chapman and Hall, London).
9. J.W. Munson- Pharmaceutical Analysis: Modern methods –Part A and Part B (MarcelDekker, Inc., New York).
10. Introduction to Spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.
11. Analytical chemistry: A Modern Approach to Analytical Science, 2nd edition by Kellner,Mermet, Otto, Valcarcel Wiley ECH.
12. Ewing's Analytical Instrumentation Handbook, 3rdedition, edited by Jack, Cazes, Marcel Dekker.
13. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical Formulations (VBS Publishers, Delhi).
14. Pharmacopoeia of India (latest edition).
15. United State Pharmacopoeia (latest edition).
16. British Pharmacopoeia (latest edition).
17. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBSPublishers Delhi)
18. F. D. Snell and C. T. Snell- Colorimetric Methods of analysis (Van Nostrand Reinhold Company, N.Y.).

SUJECT NAME: RESEARCH METHODOLOGY; REGULATORY AFFAIRS AND NEW DRUG APPLICATION
SUBJECT CODE: 08205101

Objective of the course:

The objective of the course is to introduce the basic methods of conducting research, explore ideas in formulating research objectives / hypotheses and guiding the researchers to take up research studies in a structured manner. Also it is intended to facilitate for the development of an insight into different statistical tools for data analysis, interpretation and presentation of reports in different areas of research. Research Methodology as a subject should also help researchers to prepare scientific reports for publications, presentations, cost analysis for the project, feasibility of research project, writing proposals for procurement of grants, significance of collaborative research between industry and academic institutions, and understanding of research ethics and morals.

Regulatory Affairs courses are conceptualized with vision to create effective Regulatory Affairs for Pharma Market.

Students learning outcomes/objectives:

A] Knowledge:

1. To impart clear understanding on various essential elements of Drug Regulatory Affairs.
2. To provide theoretical knowledge on various essential topics: Regulatory Introduction and Authorities, Regulatory Requirements, ICH Guidelines etc.
3. The learner will have knowledge of fundamentals & history of drug regulatory requirements in India and other countries.
4. The learner is able to understand the need of the documents & process required to file a new product in various countries.
5. Analyze how emerging developments and trends are reshaping medical device regulations
6. Regulatory approval process and registration procedures for drug products in US, EU, Japan, Australia, UK and Canada

THEORY: 4 hrs/week

(RESEARCH METHODOLOGY)

S. No.	Topics	Hours Allotted
1.	**INTRODUCTION TO RESEARCH** Introduction to research and research methodology: Meaning of research, Objectives of research, Motivations in research, different types of research, research approaches, steps involved in research process, Significance of research.	**2**
2.	**LITERATURE SURVEY & RESEARCH PROBLEM FORMULATION** Purpose, Methods and Use of literature survey, locating relevant information, use of library & electronic databases, patent data base, preparation & presentation of literature review, research article reviews, identification of gaps in research, selecting the problem, formulation of research problem, definition of research objectives, preparing research proposals	**8**
3.	**SCIENTIFIC WRITING & PRESENTATION** Research report and thesis writing (Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references), types of research paper (research articles, review article, short communications), instructions to Authors, steps involved in the process of publications (registration, new article submission, submitting articles electronically, review process, tracking the process, submitting revised articles), importance of publishing a research paper, Citations, Citation index, Quality indices, Impact factor, etc. Importance, types, content, posters, oral presentation, importance of body language -posture, gestures, eye contact, facial expressions, stage, fright, volume, pitch, speed, pause & language, visual aids & seating, questionnaire.	**9**
4.	**PROJECT PROPOSALS** a) **COST MANAGEMENT:** Different types of cost, Cost analysis of the project- cost incurred on raw materials, procedure, instrumentations & clinical trials. b) **RESEARCH GRANTS**:Introduction to various research funding organization and their funding schemes (AICTE, UGC, CSIR, ICMR, DST, DBT, GUJCOST, etc.) c) **INDUSTRY- INSTITUTION COLLABORATION:** Industrial-institution interaction, Industrial projects, significance, feasibility reports.	**8**

	d) **MORALS:** Issues related to plagiarism, collaborative models and ethics, acknowledgements.	
5.	**INTRODUCTION TO EXPERIMENTAL DESIGN** Basic Biostatistics used in experimental design: Study of F Test, t test, Chi Square Test, ANOVA and Normal Distribution in Pharmacy. Numerical Problems related to above. Introduction to Design of Experiments, Terminologies used in Experimental Design such as factors, levels, confounding, Response, Screening, Optimization, etc. Application of Experimental Design in various pharmaceutical fields. Methods of selection of different designs. Screening studies using Placket and Burman Design and Taguchi Design.	**7**
6.	**FACTORIAL DESIGN, RESPONSE SURFACE METHODOLOGY & APPLICATIONS** Full and fractional factorial designs, Design layout, How to implement the Design in Pharmaceutical Research. Evolution of full and reduced mathematical models in experimental design. Application of Factorial Designs. Introduction to Central Composite Design, axial points prediction, Contour Plots, 3D Plots, Box Behnken Design and Validation of optimized model. Application of Response Surface Methodology. Parallel, Crossover Designs and clusters designs used in clinical trials and their applications.Pharmacoinformatics, Methodology, Tools and Application in Pharmacy field.	**8**
7.	**INTRODUCTION TO PATENTS, PATENT CLAIMS & PATENT WEBSITES** Patents Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Introduction to Patent Claims, Drafting of patent claims, important patent related websites. How to search Patents in different websites.	**5**
8.	**TRADEMARK PROTECTION AND WO PATENTS** Brief introduction to trademark protection and WO patents, Introduction to “The Patents Act 1970” and “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent application.	**3**

REFERENCE BOOKS:

1. Research Methodology : Methods & Techniques, C.R. Kothari, ViswaPrakashan,

2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications.

3. Pharmaceutical Statistics: Practical and Clinical Applications, Sanford Bolton and Charles Bon.

4. Thesis projects in Science & Engineering – Richard M. Davis.

5. Thesis & Assignment – Jonathan Anderson

6. Writing a technical paper- Donald Menzel

7. How to Write a Thesis: Murray, R. Tata McGraw Hill

8. Writing For Academic Journals, Murray, R., McGraw Hill International.

9. A Handbook of Academic Writing, Murray, R. and Moore, S., Tata McGraw Hill International

10. Writing for Publication, Henson, K.T., Allyn& Bacon.

11. Effective Business Report Writing –Leland Brown

12. Manual for evaluation of industrial projects-United Nations

13. Manual for the preparation of industrial feasibility studies

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

15. Protection of industrial Property rights- P. Das &Gokul Das

REGULATORY AFFAIRS AND NEW DRUG APPLICATION

Chapter No.	Topics	Hours Allotted
1	Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.	**02**
2	Legislation to regulate, import, manufactures distribution and sales of drugs, cosmetics- The Drugs & Cosmetic Act 1940 & rules 1945 with amendments.	**03**
3	Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.	**02**
4	Quality safety and legislation for cosmetic and herbal products	**02**
5	Aims, objects and salient features of following legislations governing Pharmaceutical Industry-	

	A. Pollution Control Act B. Prevention of Food Adulteration Act 1954 C. Industrial Development & Regulation Act 1951 D. Consumer Protection Act E. The Drug Prices Controls Order, 1955 and National Pharmaceutical Pricing Authority	**01** **01** **01** **01** **01**
6	Standard institutes & certification agencies like ISI(BIS), ASTM, ISO, WHO, US-FDA, UK-MHRA, TGA	**03**
7	Drug Master File	**02**
8	Material Safety Data Sheet (MSDS) preparation	**02**
9	Industrial Safety & Health Guide lines for filing in countries like US & EU	**02**
10	Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US, EU, Japan, ICH	**03**
11	Indian pharmacopoeia, Indian Pharmacopoeia commission, IP review process, Guideline for formation of monograph, IP reference substances	**03**
12	Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP	**03**
13	Overview of ICH guidelines with special emphasis on Quality guidelines; Study of ICH common technical documents.	**03**
14	A)New Drug Application & Approval in India from CDSCO as per schedule Y & related provisions. B) Approval of new drugs: Investigational New Drug (IND) submission, format & content of AND, content of Investigator Brochure, general consideration of New Drug Approval (NDA) specific requirements, content & format of NDA, manufacturing control requirement of NDA.	**08**
15	Scale up operations, SUPAC guide line.	**02**

References Books:

1. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
2. P. Warayan, Intellectual Property Laws, Eastern Law House.
3. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)

4. Ira R. Bery, “Introduction to the Pharmaceutical Regulatory Process”, Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
5. The Drugs and Cosmetic Act 1940 – Vijay Malik 9. Indian Pharmacopoeia, Vol. 1-3, 2007.
6. The Indian Pharmacopoeia commission, Gahaziabad, Govt. of India.
7. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
8. Pollution Control Act, 1974
9. Prevention of Food Adulteration Act 1954
10. Industrial Development & Regulation Act 1951
11. Consumer Protection Act 1986

12. “WHO Expert Committee on specification on Pharmaceutical Preparation”34th report, Geneva, World Health Organisation, 1996 (WHO Technical Report Series, No. 863
13. . Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
14. A.C. Cartwright and Brian Mathews,”International Pharmaceutical Registration” Taylor and Francis Ltd. UK, 2002
15. United State Pharmacopoeia (USP) 32,NF27, 2009
16. . Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication

17. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
18. P. Warayan, Intellectual Property Laws, Eastern Law House.
19. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. **Text Books:**

Text Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9
3. Deshpande S.W., Drugs and Cosmetic Act.1940. th Ed., VallabhPrakashan

SUJECT NAME: PHARMACEUTICAL EVALUATION TECHNIQUES

SUBJECT CODE: 08205102

Objective of the course:

On completion of following theory topics & laboratory experiments, learner should be able to acquire following knowledge and skills:

Students learning outcomes/objectives:

A] Knowledge:

1. Illuminate relevance & significance of Pharmaceutical Evaluation Techniques to Pharmaceutical

Sciences.

2. Describe application of analytical methods to product from genetic engineering, amino acid sequescing, isoelectric focusing etc.

3. .Explain basic concepts of related substances and impurities present in drugs and their effect on drug stability and therapeutic action.

4 Clarify Applications of various analytical techniques in preformulation analysis.

5. Explain Analysis of solid oral dosage form and injectable dosage form.

6. Explain concept for Compendial testing and Automated analysis

7. Understand the basic concepts of evaluation of crude drug and herbal formulation.

8. Explain concept for quality control of radio pharmaceuticals and analysis of cosmetics.

9. Describe application of analytical methods for estimation of drugs in biological fluid with its application.

B] Skill:

1. Clarify and understand the assay of Ibuprofen Tablet, Tolbutamide Tablet, and Calcium Lactate

and Ferrous Fumerate as per I.P.

2. Understand the determination of water content and chloride content in pharmaceuticals.

3. Develop practical hand in quality control test for tablets, capsules, injectable dosage forms, ointments, suppositories.

4. Clarity for determination of Preservatives, Antioxidants and Colouring materials in

Pharmaceuticals.

5. Develop practical hands in determination of related substances.

6. Understand the determination of active constituents in crude drugs.

7. Explain the basic concept for quality Control tests for some herbal formulations and some cosmetics.

THEORY: 3 HOURS/WEEK

Chapter No.	Topics	Hours Alloted
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.	**06**
2	Biological Standardization: General Principles, Scope & limitations of Bioassays. Bioassays of some official Drugs.	**06**
3	Analysis of drugs and its metabolites from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Application including Bioequivalence study, Bioavailability, Pharmacokinetic etc.	**09**
4	Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.	**10**
5	Applications of various analytical techniques in preformulation analysis and its importance. \	**06**
6	Analysis of solid oral dosage form	**06**
7	Analysis of injectable dosage form	**05**
8	Compendial testing	**06**
9	Automated analysis	**04**
10	Compendial methods for evaluation of crude drug and herbal formulation	**05**

11	Quality control of radio pharmaceuticals and radio chemical method in analysis.	**06**
12	Analysis of cosmetics	**06**

PRACTICAL (6 HOURS/WEEK)

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
2. Antimicrobial assay of Streptomycin.
3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. PK studies- Exercises based on problem given. IVIVC Biowaiver.
6. Extraction of drugs and measurements.
7. Bioequivalence comparison.
8. Determination of Water in Sorbitol, Sodium Citrate, Ampicillin etc.
9. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
10. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
11. Determination of related substances in Albendazole, Amiloride, Metronidazole, Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P.
12. Determination of active constituents in crude drugs. eg. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
13. Quality Control tests for some herbal formulations.
14. Quality Control tests for some cosmetics.
15. Any other relevant exercises based on theory.

REFERENCE BOOKS:

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. Mark C. Rogge and David R Taft, “Prclinical Drug Development”, Drugs and Pharm. Sci.
Series, Vol. 152, Marcel D

8. Ekker Inc., N.Y. 11. 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.

9. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.

10. Welling and Tse.-Pharmacokinetic

11. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, 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.
16. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs andPharmSci.Series,Vol. 160, Taylor and Francis, 2006 N.Y.
17. S. Ahuja, Modern Pharmaceutical Analysis
18. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
19. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
20. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
21. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
22. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
23. Indian Pharmacopoeia,Vol. I and Vol. II - 1996.The Controller of Publications; New Delhi, Govt. of India,
24. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
25. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
26. Basic tests for pharmaceutical substances – WHO (1988)
27. Basic tests for pharmaceutical dosage forms – WHO (1991)

28. Phytochemical Methods by J.B.Haroborne
29. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine &
Homeopathy)

TEXT BOOKS:

1. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi..

2. Gibaldi and Perrier-Pharmacokinetics

SUJECT NAME: GMP AND VALIDATION

SUBJECT CODE: 08205103

Objective of the course:

On completion of following theory topics & laboratory experiments, learner should be able to acquire following knowledge and skills:

Students learning outcomes/objectives:

A] Knowledge:

1. Explain basic concepts and principles of manufacturing facilities.

2. Understand the basic concepts of sterile products GMP.

3. Learning of good practices of distribution of the drug.

4. Understand the requirement of QA, QC, Production, Stores and maintenance departments of Pharma industry

5. Basic concepts of GLP.

6. Learning of good practices of warehousing of the drug.

7. Importance of different types of validation and impact on public health

8. Understanding of validation of manufacturing process of pharmaceutical dosage form.

9. Knowledge of various validation procedures related to equipments, utilities, cleaning procedures, computer system and analytical method.

10. Understanding of basic concepts of product development of different dosage form and product scale up.

B] Skill:

1. Clarify and understand the correct use of laboratory equipments with calibration of various apparatus used in laboratory together with safety measures to be followed.
2. Develop practical hand in validating different equipments and instrument
3. Acquire skill in validating analytical method

THEORY: 3 HOURS/WEEK

Chapter No.	**Topics**	**Hours Alloted**
1.	Concepts of Philosophy of QA, GMP, GLP	**02**
2.	GMP: a. Organization & Personnel, responsibilities, training, hygiene	**02**
3.	GMP: 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	**02**
4.	GMP: c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).	**02**
5.	GMP: d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms	**02**
6.	GMP: e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities	**03**
7.	GMP: f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for	**03**

	various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc	
8.	GMP: g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials	**02**
9.	GMP: h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, Specifications for materials, intermediates and finished product; data generation and storage, quality control documents, retention samples, records, audits of quality control facilities	**03**
10.	GMP: i. Finished product release, quality review, quality audits	**02**
11.	GMP: j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management	**02**
12.	GMP: k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing	**02**
13.	GMP: l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents	**02**
14.	GMP: m. Waste disposal, scrap disposal procedures and records	**02**
15.	Good Laboratory Practices	**02**
16.	WHO certification	**02**
17.	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	**06**
18.	Calibration Master plan, Validation of Equipment Concept of URS, DQ, IQ, OQ & PQ. Validation of following equipments - Dry Powder Mixers -Fluid Bed and Tray dryers	**11**

	-Tablet Compression (Machine) - Dry Heat Sterilization/Tunnels - Autoclaves - Membrane filtration - Capsule filling machines - Validation of Integrated lines by media fill test - Validation of existing equipment	
19.	Utilities Validation: a. Validation of Pharmaceutical Water System & pure steam, b. Validation of HVAC system c. Validation of Compressed air.	**05**
20.	Cleaning Validation: Cleaning of Equipment, Cleaning of Facilities	**04**
21.	Analytical Method Validation; General principles of analytical method validation. Validation of following analytical Instruments: - HPLC - Dissolution test apparatus - U.V./Visible spectrophotometers	**06**
22.	Process Validation Prospective, concurrent, retrospective & revalidation, Process validation of following formulations - Coated tablets - Capsules - Ointment/Creams - Liquid Orals	**06**
23.	Computer System Validation	**02**

PRACTICALS: 6 HOURS/WEEK

1. Preparation of SOPs.

2. Preparation Of Standard testing procedures.

3. Preparation of specifications.

4. Preparation of Validation protocol.

5. Preparation of validation report.

6. Preparation of other syllabus relevant QA documents like SMF, MFR etc.

7. Pre-formulation studies of a model Drug.

8. Validation of analytical method (HPLC, UV, Visible, Multicomponent assay method).

9. Cleaning validation of one equipment.

10. Validation of at least two analytical instruments (eg. HPLC, UV, IR)

11. Validation of following equipment

a. Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet Compression Machine

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. GMP practices for pharmaceutical-James Swarbrick

5. Remingtons “Pharmaceutical Sciences”.

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. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A.Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.

9. Michael Levin, Pharmaceutical Process Scale-Up”, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

10. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

11. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (MarcelDekker)

Text Books:

1. P. P .Sharma “How to practice GMPs”, 3rd edition Vandana Publication.

2. P. P. Sharma “How to practice GLP” Vandana Publication.

3. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci.Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.