M. PHARM REVISED SYLLABUS
(2008-2009)

EFFECTIVE FROM 2008-2009
ACADEMIC YEAR ONWARDS

UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
KAKATIYA UNIVERSITY, WARANGAL-506 009.

KAKATIYA UNIVERSITY
WARANGAL

RULES AND REGULATIONS TO M.PHARM. COURSES OFFERED UNDER SEMESTER SYSTEM

General Schedule

There shall be 16 weeks for each semester and it takes two years to complete the course. III and IV semester contains the project work

Academic Schedule

Each semester will have **4 theory and two practical papers** with **six periods** per week. There also seminars and assignments in I and II semester and comprehensive viva in third semester

Question Paper Pattern

There will be **four questions** in each paper. Each question will have 3 bits

Distribution of marks:
I and II semester (4 theory and 2 practical and seminar and assignment)
Theory

Four question	4x25=100 marks

Practicals:

	100 marks
Seminar	50 marks
Assignments	50 marks
III semester seminar	50 marks

Comprehensive viva voice 50 marks

IV semester seminar 50marks
Disseratation evaluation 200 marks
Disseration viva voice 50 marks

Promotion:

A student has to not only put in 75% of attendance and register for examination for each semester but also appear all paper in each semester for promotion to next semester. A students with 4 papers has block lag can be promoted to M.Pharm second year. There shall be no supplementary examinations.

The minimum pass marks shall be 50% in each paper (Theory & Practicals) separately.

Award of division

Aggregate marks of all the semesters:

I Division with Distinction ----- 75% and above
I Division ……. 60% and above and below 70%
II Division ……. 55% and above and below 60%
III Division (PASS) ……. 50%

A candidate in order to become eligible for I/II division shall be required to pass all the papers of final semester in one attempt, besides passing I/II/III semester papers, either earlier to or along with the final semester.

Whenever the syllabi and scheme of examination are changed, in such cases two examinations will be conducted as per old syllabus and scheme. Thereafter, the candidates who have availed/ not availed and not qualified shall have to take the backlog papers as per the changed syllabi and scheme of examination.

The candidates who could not put up required percentage of attendance and detained, however be eligible to seek readmission in the same semester (with at least 40% of attendance in aggregate). Such students have to pay 50% of the tuition fee prescribed.

Distributions of papers:

I semester …….. All papers compulsory
II semester …….. All papers compulsory
III semester (Seminar
Comprehensive viva voice)
IV Semester project work

Improvement:

a) Improvement during the course of study

"A candidate who has passed in the papers of I/II/ semesters completely can improve his /her performances in one or more papers of I/II/ semesters in the immediately following examination with the provision to retain the better of the two".

Important Guidelines:

1. There shall be four major subjects and two practical during the first two semesters.

2. One seminar and one assignment will be conducted during each semester (I&II). Each will be evaluated for 50 marks by three average of it is taken for awarding marks.

3. One seminar pertaining to the topic of dissertation including concept, literature plan of work will be conducted at the end of IIIrd semester and will be evaluated by minimum of three PG teachers which would include the concerned supervisor. The average marks will be taken into account.

4. Thesis marks will be awarded only by the external examiners.

5. The viva-voce marks are to be awarded by the supervisor and external examiner jointly.

6. Comprehensive viva shall be conducted at the end of third semester and evaluated by the external examiner and all faculty members within each specialization.

7. One assignment related to specialization (related to specific topics and supported by original articles) is given in each of I & II semesters, which shall be evaluated by two examiners. Average marks is taken into account.

8. One seminars each semester during I & II shall be conducted before all the faculty and PG students and will be evaluated by minimum of three PG teachers. Average marks are taken into account.

9. There shall be two practical examinations each of six hours duration on two consecutive days at the end of first and second semesters. There shall be one internal examiner for each practical examination. However, the external examiner shall be common for both the practical examinations.

SPECIALIZATIONS:

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacognosy
4. Pharmacology
5. Industrial Pharmacy
6. Pharmacy Practice
7. Pharmaceutical analysis

M.Pharm. I Semester

Theory	Marks	Lectures	Tutorials	Practicals
Paper – I	100	3	2	-
Paper – II	100	3	2	-
Paper – III	100	3	2	-
Paper – IV	100	3	2	-
Practicals				
Paper – I	100	-	-	9
Paper – II	100	-	-	9
Seminar	50			
Assignment	50			
Total	**700**	**12**	**8**	**18**

M.Pharm. II Semester

Theory	Marks	Lectures	Tutorials	Practicals
Paper – I	100	3	2	-
Paper – II	100	3	2	-
Paper – III	100	3	2	-
Paper – IV	100	3	2	-
Practicals				
Paper – I	100	-	-	9
Paper – II	100	-	-	9
Seminar	50			
Assignment	50			
Total	**700**	**12**	**8**	**18**

M.Pharm. III Semester

	Marks
Seminar (Pertaining to the topic of research and work plan)	50
Comprehensive viva-voce	50
Total	**100**

M.Pharm. IV Semester

	Marks
Seminar (Experimental Work, Results, Discussion and Conclusion)	50
Dissertation evaluation	200
Dissertation Viva-Voce	50
Total	**300**

M.PHARM. (PHARMACEUTICAL ANALYSIS)

I SEMESTER

Theory		**hours/week**
1.1.T	Advanced Pharmaceutical analytical techniques	3
1.2.T	Pharmaceutical Analysis-I	3
1.3.T	Quality control of Pharmaceutical dosage forms	3
1.4.T	Biological standardization	3

Practicals

1.1.P	Advanced Pharmaceutical analytical techniques	9
1.2.P	Pharmaceutical Analysis-I	9

II SEMESTER

Theory

2.1.T	Quality assurance	3
2.2.T	Pharmaceutical Analysis-II	3
2.3.T	Analytical method development and validation	3
2.4.T	Regulatory Affairs	3

Practicals

2.1. P	Analytical method development and validation	9
2.2.P.	Pharmaceutical Analysis-II	9

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

1.1. T. ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES

Unit I

a. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds and applications for pharmaceutical analysis
b. HPTLC: Theory, instrumentation and various applications for pharmaceutical and herbal products.
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative analysis
d. Electrophoresis: Theory, instrumentation and various techniques (e.g. paper, capillary electrophoresis etc.) applications for analysis pharmaceuticals.

Unit II

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: Preparation and operation, detectors, derivitazation and pharmaceutical applications: GC-MS and application mentioned for the substances in IP.
b. HPLC: Principles and instrumentation, columns and detectors used, pharmaceutical applications.
c. LC-MS, MS-MS and its applications for analysis or drug substances as mentioned in IP, BP and USP.

Unit III

a. UV-Visible spectroscopy : Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy.
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications.

Unit IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, interpretation of spectra and applications for identification and structure determination.

Unit V

NMR: Theory, instrumentation, and it applications in analysis of pharmaceuticals

REFERENCES:

1) Instrumental Methods of Chemical Analysis - B.K Sharma
2) Organic spectroscopy - Y.R Sharma
3) A Text book of Pharmaceutical Analysis - Kerrenth A. Connors
4) Vogel's Textbook of Qualitative Chemical Analysis - A.I. Vogel
5) Practical Pharmaceutical Chemistry - A.H. Beckett and J.B. Stenlake
6) Organic Chemistry - I. L. Finar
7) Organic spectroscopy - William Kemp
8) Quantitative Analysis of Drugs - D.C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations - P. D. Sethi
10) Spectrophotometric identification of Organic Compounds - Silverstein
11) HPTLC - P.D. Seth
12) Indian Pharmacopoeia - 2007

Practicals

1.1 P Advanced Pharmaceutical analytical techniques: The experiments should be conducted based on theory

1.2.T. PHARMACEUTICAL ANALYSIS – I

Unit I

An advanced study of the principles and procedures involved in Non – aqueous, Complexometric, Oxidation – reduction and Diazotization methods

Unit II

An advanced study of the principles and procedures involved in the electrometric methods: Conductometry, Potentiometry, Polarography and Amperometry

Unit III

Detailed study of the principles and procedures involved in the quantitative determination of the organic functional groups: Amines, Aldehydes, Ketones, Ester and Hydroxy

Unit IV

Principles and procedures involved in using the following reagents in pharmaceutical analysis with suitable examples

i. MBTH(3-methyl – 2- benzothiazolone hydrazone)
ii. F.C. Reagent (Folin – Ciocalteau)
iii. PDAB (Para Dimethyl Amnio Benzaldehyde)
iv. 2,6 – Dichloroquinone Chlorimide
v. 2,3,5 triphenyl tetrazolium salt
vi. 1,2 napthoquinone-4-sulfonate reagent

Unit V

Principles and Procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of the Alkaloids (Pilocarpine and quinine sulphate) Antibiotics (Cephalosporins, Griseofulvin), Vitamins (Vitamin A and Vitamin E), Glycosides (Sennoside and Diosgenin), Steroids (dexamethasone and estrogens) and Diuretics (Spiranolactone, Frusemide).

REFERENCES

1) Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2) Pharmaceutical Chemistry – Becket and Stanlake
3) Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
4) Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5) Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6) Indian Pharmacopoeia – 1996
7) Instrumental Methods of Chemical Analysis – B.K. Sharma
8) A Text Book of Pharmaceutical – Kenneth A. Conners
9) Journals (Indian Drugs, IJPS etc.)

Practicals

1.2 P Pharmaceutical analysis-I: The experiments should be conducted based on theory

1.3.T. QUALITY CONTROL OF PHARMACEUTICAL DOSAGE FORMS

Analysis of Pharmaceutical Dosage form monographs as mentioned in various Pharmacopoeias (I.P., B.P., E.P and U.S.P)

Unit I

Solid dosage forms (Tablets, Capsules, Powders), Semisolid dosage forms (Ointments, Creams)

Unit II

Liquid oral preparations,(suspensions, gels, Emulsions, solutions and elixirs) Eye/Ear and Nasal Drops

Unit III

Parenterals (large volume and small volumes), Inhalations (Aerosols, Nebulizers)

Unit IV

Topical preparations, Transdermal drug delivery systems, Sprays, Suppositories, Pessaries, Surgical Dressings, Novel Drug Delivery Systems

Unit V

Various in process quality control tests carried on the following dosage forms
Tablets, capsules, parentrals, Liquid orals and other dosage forms

RECOMMENDED BOOKS:

1) Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2) Microbiological Assays – Barton J. Wright
3) Pharmaceutical Chemistry – Becket and Stanlake
4) Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
5) Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
6) Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
7) Indian Pharmacopoeia – 1996

1.4 T. BIOLOGICAL STANDARDIZATION

Unit-I. Detailed study of principles & procedures involved in bio assay of.

(a) Heparin, Insulin, Posterior Pituitary
(b) Diphtheria, Typhoid0

Unit-II. Principles and Procedures involved in Biological tests of the following.

(a) Living contaminants in vaccines.
(b) Endotoxins
(c) Histamine like substances
(d) Toxic elements

Unit-III Microbiological assay of
(a) Vitamins e.g.cyanocobalamin
(b) Antibiotics such as Neomycin sulphate,
(c) Vaccine e.g. Diptheria

Unit-IV

a) Biological assay evaluation of oxytocin, rabbies vaccine and tetanus antitoxin

b) Radioimmuno assay: General principles, scope of limitations R.I.A of Insulin and digitalis, ELISA (instrumentation, Principle and application for analysis of pharmaceuticals)

C) Radiopharmaceuticals (indium (^{111}In) pentetate injection, strontium (^{89}Sr) chloride injection, Technitium (^{99m}Tc)macrosalib injection

Unit-V

Detailed study of principles & procedures involved in bio assay of estrogens, Hepatitis vaccine, Biological assay of Gas-gangrene antitoxin, Blood and blood related products(Anti-blood grouping serum, Human albumin, Human plasma protein fraction, Human coagulation factors), Biotechnology products(erythropoietin, Interferons, streptokinase).

Books Material Recommended

1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
2. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
3. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
4. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
5. Pulok K Mukherjee: Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publishers, New Delhi.
6. British Pharmacopeia, Department of Health U.K.
7. Classification of cosmetic raw materials

2.1. QUALITY ASSURANCE

Unit I

Concept of quality assurance, total quality management, philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NBL and OSHA 18000

Unit II

a. Organization and personal, responsibilities, training hygiene
b. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile area, control of contamination
c. Equipments: selection, purchase, specifications, maintenance, clean in place, sterilized in place - Raw – materials; purchase specifications, maintenance of stores, selection of vendors, controls and raw materials

Unit III

Manufacture and controls on dosage forms

a. Manufacturing documents, master formula records, batch formula records, standard operating procedures, Quality audits of manufacturing processes and facilities
b. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.
c. Guideline for Quality Assurance of Human Blood Products and large volume parenterals.

Unit-IV

a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities – finished products release: quality review, quality audits and batch release document.

Unit V

a. Distribution and Distribution records: Handling of returned goods recovered materials and reprocessing.
b. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.

2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.1 and Vol.2, WHO (1999)
3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash

REFERENCE BOOKS:

1. Basic tests for Pharmaceutical substances – WHO (1988)
2. Basic tests for Pharmaceutical substances – WHO (1991)
3. How to practice GMP's – P.P.Sharma
4. The Drugs and Cosmetic Act 1940 – Vijay Malik
5. Q.A. Manual - D.H. Shah
6. SOP Guide lines - D.H. Shah
7. Quality Assurance Guide - OPP

2.2. PHARMACEUTICAL ANALYSIS - II

Unit I

An advanced study of the principles and procedures and applications of instrumental methods in the development of medicines (GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS)

Unit II

a) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,
b) X-ray spectroscopy: x-ray diffraction, principle, instrumentation , method and application for the analysis of pharmaceuticals

C) Optical rotator dispersion technique for the analysis of chiral compounds

Unit III

An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame Photometry, Fluorimetry, Nephelo - Turbidimetry and Refractrometry, Study of general principles and methods for the determination of Proteins, Carbohydrates, Fats, Crude fibre, Moisture and Nitrogen

Unit IV

Thermal method of analysis, theory, instrumentation and applications of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA) and DSC.

Unit V

Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation

Methodology involved

a. Moisture content determination in dosage forms
b. Alcohol determination
c. Essential oil determination
d. Surfactant analysis

REFERENCES:

1. Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2. Pharmaceutical Chemistry – Becket and Stanlake
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
4. Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5. Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6. Indian Pharmacopoeia – 1996
7. Instrumental Methods of Chemical Analysis – B.K. Sharma
8. A Text Book of Pharmaceutical – Kenneth A. Conners

2.2. P. Pharmaceutical Analysis – II. The experiments should be conducted based on theory

2.3. ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

Unit-I

Analytical method development: Introduction, quantification of calibration of various analytical instruments for drug analysis and maintenance of Instruments

Unit-II

Analytical methods development, optimization and validation using the instruments such as UV/Vis spectrometer, FT-IR spectrometer for pharmaceutical dosage forms, active pharmaceutical ingredients (API) and pharmaceutical aids.

Unit-III

Development of analytical method, optimization and validation using Paper and Thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.

Unit-IV

Drug analysis from biological samples, extraction using various extraction techniques and Development, optimization and validation of bioanalytical method.

Unit V

Validations

Concept, Type of Validations, Master plan, Protocol for process, cleaning, equipment and facilities including sterile and non-sterile areas, analytical method validations, vendor validation and audit, sample testing and trade analysis.

Prevalidation activities: Protocol preparations, protocol executions, Deviations and Change Controls, Summary and Certification, Revalidations.

Recommended books:

1. Analytical Method Development and Validation, Michael Swartz, Swartz Swartz, Michael Swartz, CRC press.1997
2. Modern HPLC for practicing scientists, Michael W.Dong (google.com)
3. Practical HPLC method development 2nd edition , Llyod R.synder (google.com)
4. Pharmaceutical process validation, NashRA and Watcher AH, CBS publishers and Distributors, Newdelhi
5. Modern Pharmaceutical analysis, Volume1-4, Satish Ahuja, CBS publishers and Distributors, Newdelhi

2.1. P. Analytical method development and validation: The experiments should be conducted based on theory

2. 4 . REGULATORY AFFAIRS

1. New Drug Application: Steps involved in the development of a new drug. Procedure for submission of new drug application (NDA) and abbreviated NDA. Requirements and guidelines on clinical trials for import and manufacture of drug products as per Drugs and Cosmetics act. Clinical trials, study design, documentation and interpretation.

2. Documentation: Importance of documentation, statutory requirement and procedure for documentation, description of documents generated in manufacture of pharmaceutical dosage form.

3. Current good manufacturing practices (CGMP) as per WHO.

4. Good laboratory practices (GLP)

5. ISO 9000 series, GATT, TQM

6. Intellectual property rights and Patent laws in India

M. Pharm (Pharmaceutics)

I SEMESTER	**Th. hrs/week**	**Pr. hrs/week**
1. Bio Pharmaceutics & Pharmacokinetics	3	9
2. Pharmaceutical Formulation Technology *	3	9
3. Physical Pharmaceutics *	3	-
4. Quality Assurance (optional)	3	-
5. Seminars/Assignments	3	3

II SEMESTER		
6. Novel Drug Delivery Systems-I	3	9
7. Novel Drug Delivery Systems-II *	3	9
8. Pharmaceutical Equipment *	3	-
9. Cosmetic Technology/ Regulatory affairs (optional)	3	-
10. Seminars/Assignments	3	3

* **Practicals for both papers**

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar on Dissertation (Results)
Dissertation

I - Bio Pharmaceutics & Pharmacokinetics: 3 hrs/week

1. Bio-availability, Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Tests of significance, Test, ANOVA.

2. Physico-Chemical properties affecting bioavailability, pH-partition theory, dissolution, surface area, adsorption, complexation, polymorphism etc., and techniques of enhancing dissolution rate.

3. Formulation factors affecting bioavailability of drug in dosage forms of tablets, capsules, Parenterals, liquid orals and topical dosage forms.

4. Basic concepts of Pharmacokinetics: Compartmental models: one, two and non compartmental approaches to pharmacokinetics. Recent trends, merits and limitation of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

    i. Absorption: (wherever applicable) Absorption rate constant. Absorption half life, lag time and extent of absorption, AUC.

    ii. Distribution: Apparent volume of distribution and its determination.

    iii. Metabolism: Metabolic rate constant and its determination.

    iv. Elimination: Over all apparent elimination rate constant and half life.

    Under the following conditions:

    a) Intra venous bolus injection

    b) Intra venous infusion

    c) Single dose oral administration

    d) Multiple dose injections

    e) Multiple dosage oral administration

    v. Non invasive methods of estimating pharmacokinetic parameters with emphasis on salivary and urinary compartments.

    vi. Concept of clearance: Organ clearance, total clearance, hepatic clearance, gut wall clearance, lung clearance and renal clearance.

5. Non-linear Pharmacokinetics: concepts of linear and non linear pharmacokinetics, Michaelis-Menten kinetic characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological response.

6. Non compartmental Pharmacokinetics.

7. Time dependent Pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chrono Pharmacokinetics.

8. Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver, and renal diseased states.

Practicals: Based on Theory.

II- PHARMACEUTICAL FORMULATION TECHNOLOGY 3hrs/week

1. Performulation studies:

a) Goals of preformulation, preformulation parameters, Methodology, Solid state properties, Solubility and Partition coefficient, Drug excipient compatibility.
b) Excipients used in pharmaceutical dosage forms.
c) Properties and selection criteria for various excipients like surfactant, viscosity promoters, diluents, coating materials, plasticizers, preservatives, flavors and colours.

2. Formulation Development:

a) Solid dosage forms: Improved production techniques for tablets: New materials process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

b) Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalations dosage forms.

c) Liquid and Semi-solid dosage forms: Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions, dry syrups and semi-solid dosage forms.

d) Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.

e) Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

f) Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

III. Physical Pharmaceutics: 3hrs/week

1. **Theory of Solubilization and Solubilization Techniques:** Solubility and solubilization of non electrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation.

2. **Theories of Dispersion:** Solid-liquid dispersion: adsorption, wetting, crystal growth mechanisms and prevention of crystal growth.

3. **Emulsion:** Formation and stability of emulsion with special emphasis on electrical theory, HLB theory and dielectric properties. Preparation, evaluation and applications of multiple and microcmulsions.

4. **Solid State Properties:** Crystal properties and polymorphism, Techniques for study of Crystal properties, solid state stability, flow properties of powders, segregation and its importance.

5. **Theories of Compaction and Compression:** Compression, consolidation strength of granules, compression and consolidation under high loads, effects of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.

6. **Polymer Science:** Polymer structure, classification and Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state. Applications of polymers in pharmaceutical formulations.

7. **Diffusion and Dissolution:** Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, Thermodynamics of diffusion. Dissolution: Basic theories of dissolution, models. Sink conditions in dissolution and its importance. In-vitro-in-vivo- correlations. Dissolution testing for Novel drug delivery systems.

8. **Kinetics and Drugs stability:** Stability calculations, rate equation, kinetics of decomposition, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms. Freeze-thaw methods, centrifugal methods, temperature and humidity control.

IV. Quality Assurance: 3hrs/week

1. **Plant Design:** Design of manufacturing facility as per current good manufacturing practices for the bulk production of different pharmaceutical dosage forms.

2. **Equipment Validation:** Installation, validation and maintenance of typical equipment used in bulk manufacture of pharmaceutical dosage forms with reference to GMP requirement.

3. **Process Validation:** Regulatory basis, validation of solid dosage forms, liquid dosage forms, and sterile products, Process validation of raw materials, validation of analytical methods.

4. **Quality Control:** Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and its applications in process control. Testing programme and methods for testing quality of pharmaceutical dosage forms. Adulteration and misbranding.

5. **Stability studies:** ICH guidelines and stability protocols for different pharmaceutical dosage forms.

6. **Industrial Safety:** Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals. Monitoring and prevention systems.

7. **Applications of optimization techniques:** Optimization parameters, statistical design and techniques in product development and evaluation. Production optimization and its importance.

V – Seminars & Assignments

II – Semester

IV-Novel Drug Delivery Systems - I

1. **Review of Fundamentals of controlled drug delivery systems:**
   Fundamentals, rationale of sustained/controlled drug delivery, factors influencing the design and performance of sustained/controlled release products, Pharmacokinetic/ Pharmacodynamic basis of controlled drug delivery. Types and structure of polymers, Use of polymers and biocompatible polymers in controlled release of active agents.
2. **Drug targeting principles and approaches:** Active and passive targeting, Tumor targeting, Bone marrow targeting, cell surface biochemistry and molecular basis of targeting. Tumourbiology-Extra cellular matrix- knowledge of cell adhesion molecules- selectins and fibronectins -lectins for tumour targeting.

   Monoclonal antibodies and engineered antibodies for drug delivery. Antibody-drug conjugates, Limitations of antibody targeting.

   Brain targeting, Blood brain barrier, structure, role in drug transport, targets for targeting.

   Receptor-structure, endocytosis, receptor mediated endocytosis and transcytosis.

   Knowledge of drug targeting through chemical drug delivery approaches to different organs like brain, eye, lung and lever etc. Colon specific systems.

3. Transdermal drug delivery systems, Iontophoresis, Electroporation and Microneedles, Gastro Retentive Drug Delivery System, oro dispersible tablets, Dendrimers.

4. **Design and fabrication of controlled release drug delivery system:**
   Principle involved and formulation of**:** Oral dosage forms – Diffusion system, Reservoir devices, Osmotic systems, Systems utilizing dissolution and ion exchange resins, prodrugs, Multiple Emulsions.

5. Parenteral dosage forms, intramuscular injections, implantable therapeutic systems, Transmucosal systems and mucoadhesive systems, Nasal delivery, intravaginal and intrauterine systems, Lung delivery systems. Ocular drug delivery, drug delivery to GIT.

6. **Carrier Based Delivery Systems:** Principle involved and formulation of Micro particulate drug carriers, Liposomes, Niosomes, Microspheres, Magnetic microspheres, Nanoparticles. Resealed erythrocytes.

Practicals: Based on theory

VII- NOVEL DRUG DELIVERY SYSTEMS - II 3 hrs/week

1. Cell membranes, epithelial barriers of Drug absorption and physiological factors affecting oral bioavailability.

    a. Plasma membrane – Phospholipids bilayer, membrane modulation of fluidity modelsvproteins.
    b. Epithlia – cell junctions – structure and role in drug absorption.
    c. Transport across cell membranes – efflux transporter systems (multi drug resistance).

2.

a) Inter cellular routes of absorption, persorption.
b) M cells and peyer's patches in GIT, mucus – structure and composition.
c) Permeation enhancers – classification and mode of action.
d. Lymphatic transport of drugs.

3. **Nucleic acid based therapeutic delivery systems:** Gene therapy, introduction, (ex vivo & in-vivo gene therapy) potential target diseases for gene therapy (inherited disorder and cancer), gene expression system (viral & non viral gene transfer), gene delivery systems (liposomal), biodistribution and pharmacokinetics. Clinical applications. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

4. **Genomics, Proteomics:** Definitions of genomics and proteomics and Bioinformatics. Brief Knowledge of Human genome project –Pharmacogenomics-genetic Polymorphisms influencing drug disposition and effect on drug response.

5. Delivery of peptides and proteins/Biotechnology based drugs:-Formulation aspects. Preformulation studies and problems: Protectants, delivery kinetics. Overview of delivery systems, site specific proteins, Stability problems, Evaluation of recombinant proteins. Knowledge of engineered proteins-techniques of getting engineered Proteins by DNA technology. Insulin derivatives like- Lispro, tissue plasminogen activator like reteplase. Antibodies, derivatives of antibodies Myelotarg, Herceptin, and Absciximab (Reopro).

6. Vaccine Delivery: Evidence and mechanism of uptake and transport of antigens. Delivery systems used to promote uptake. Absorption enhancers, Lipid carrier systems, oral immunization, peyer's patches, common mucosal immune system, controlled release micro particles for vaccine development, single dose vaccine delivery systems using biodegradable polymers. Knowledge of peptide based and nucleic acid based vaccines. Antigen adjuvants in vaccine formulations.

VIII. Pharmaceutical Equipment: 3hrs/week

Installation, Validation, Maintenance and working of the following:

1) **Tablet Machines**: Rotary tablet, Multi punch

2) **Coating Equipment**: Pans, fluidized bed

3) **Dryers**: Freeze, spray, fluidized bed and tray dryer

4) **Granulators**: Rapid mixer, extruder-spheronizer

5) **Mixers/Milling**: Planetary, double cone, triple roller mill, colloidal mill

6) **Filters:** Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room

7) **Sterilization:** Autoclave

8) **Homogenizers** and High Pressure Homogenizer

IX. COSMETIC TECHNOLOGY/REGULATORY AFFAIRS (Optinal) 3 hrs/week

1. **Preformulations studies:** Preformulation studies and stability testing of Cosmetic products – Shelf–life determination of Cosmetic products, Effects of environmental factors like light, temperatures etc., on product stability.

2. **Raw materials used for Cosmetic preparation:** Detailed knowledge of various raw materials used in cosmetic industry, like surfactants, humectants, perfumes and colours.

3. **Good Manufacturing Practices and Regulatory Requirements:** Knowledge of the Regulatory Standards governing Cosmetic products in India as well as International Markets.

4. **Hair Care Products:** Introduction, Hair structure, Antidandruff shampoos, setting lotion, Hair dyes.

5. **Skin Care Products:** Introduction, anatomy and physiology of skin, formulation of skin cleaners, moisturizers, sunscreen products, anti acne products, anti-ageing creams.

6. **Colour cosmetics:** Introduction lip sticks, nail polish, face make-up and eye make-up.

7. **Herbal Cosmetics:** Introduction, use of plants and plant materials in formulation of cosmetics with emphasis on dentifrices, skin care products and personal hygiene products.

8. **Personal Hygiene Products:** Shaving creams and after shave products, Antiperspirants and deodorants.

9. **Safety testing of Cosmetic Products:** Microbiology in Cosmetics.

   Knowledge of the various microbial contaminants in cosmetic products.

   Knowledge of various preservative systems for cosmetic products.

   Selection criteria for preservatives.

   Efficacy and safety testing of preservatives in cosmetic products.

10. **Packaging in Cosmetics:**
    Knowledge of various packaging materials used in cosmetic products.

    Knowledge of various machines used for packing of cosmetic products.

    Contemporary trends in cosmetic packaging.

    Compatibility and stability testing of packaging materials in cosmetic products.

I – Semester

Biopharmaceutics and Pharmacokinetics (Practicals) (9hrs/week)

1) Calculation of Pharmacokinetic Parameters using one compartment open model in blood when given by
   a) I.V. bolus
   b) Oral administration (Method of Residuals)
   c) I.V. infusion

2) Calculation of Pharmacokinetic parameters using one compartment open model by urinary excretion data:
   a) Rate Excretion method
   b) Sigma Minus method.

3) Calculation of absorption rate constant by Wagner-Nelson method.

4) Calculation of Pharmacokinetic parameters using Two-Compartment open model in blood when given by:
   a) Oral route
   b) I.V. route

5) Effect of formulation factors on Bioavailability of the drug from various dosage forms.

6) Comparison of Invitro-dissolution profiles of marketed preparations.

7) Effect of Polymorphism on drug dissolution

8) Determination of a protein binding of a drug.

9) Effect of Complexation on the solubility and dissolution rate of drug from dosage forms.

10) To conduct a bioequivalence study using plasma/urine/saliva samples.

I - Semester

Pharmaceutical Formulation Technology & Physical Pharmaceutics 9 hrs/week

1) Preparation and evaluation of Oral suspensions.

2) Preparation and evaluation of Effervescent tablets.

3) Preparation and evaluation of Gel based formulations.

4) Design and evaluation of a Aerosol based formulations.

5) Effect of compression force on tablet hardness and disintegration.

6) Effect of pH of dissolution medium on release rate profile of a drug.

7) Effect of various disintegrating agents and superdisintegrants on hardness, disintegration and dissolution of drug from dosage form.

8) Comparison of drug release from tablets prepared by Dry granulation, wet granulation, and slugging.

9) Comparison of Intrinsic dissolution rate with dissolution rate profile of dosage form.

Physical Pharmaceutics

1) Diffusion study of drug through various Polymeric membranes.

2) Determination of shelf life of a drug using Accelerated stability studies. (Temperature, pH and Humidity).

3) Formulation and evaluation of Multiple and Micro emulsions.

4) Enhancement of Solubilization of Non-electrolytes by
a) Surfactants b) Co-solvents c) Complexation d) Solid dispersion

5) Effect of Compression force on tablet strength, Friability and lamination.

6) Effect of various blends of glidants on flow properties of powders, granules.

7) Measurement of rheological properties of some polymers and study the influence of plasticizers.

8) Measurement of surface tension/interfacial tension to determine the CMC of surfactants.

9) Preparation of polymer solutions & studying the rheological behaviour

10) Drug-excipient interaction study using Differential scanning calorimeter.

11) Determination of log P value

II - Semester

Novel Drug Delivery Systems – I (Practicals) 9 hrs/week

1) Preparation and evaluation of Microcapsules.
2) Preparation and evaluation of Transdermal patches of a drug.
3) Preparation of evaluation of Liposomal drug delivery systems.
4) Preparation and evaluation of Bioadhesive oral dosage form.
5) Preparation and evaluation of Microspheres.
6) Preparation and evaluation of Buccal drug delivery systems.
7) Design of Protein and peptide drug delivery systems.
8) Development of matrix type sustained release drug delivery.
9) Development of controlled release dosage form for oral use.(Elementary osmotic pump).
10) Preparation and Evaluation of ODT.
11) Preparation and Evaluation of GRDDS.
12) Preparation and evaluation of a Drug immunoconjugate
13) Preparation and evaluation of solid lipid nano particles

Novel Drug Delivery Systems – II & Pharmaceutical Equipment 9 hrs/week

1) Studying the drug transport across Porcine buccal mucola/skin (hydrophilic liphilic drugs)
2) Preparation of liposomal gene delivery systems
3) Preparation of vaccine delivery systems
4) Preparation & Evaluation of stability of protein formulation by gel electrophoresis
5) Studying the role of permeation enhancers in drug transport across biological membranes
6) Preparation of a DNA vaccine
7) Validation of
8) Validation of a dryer
9) Validation of a filtration assembly (rembrne filter)
10) Validation of Rotary tablet machine
11) Validation of Aseptic room
12) Validation of a coating pan

Kakatiya University

List of Equipment Required for M. Pharm. Pharmaceutics

1) Digital Disintegration Time apparatus	1.No
2) Dissolution apparatus (U.S.P.) with 8 flasks with paddles and baskets	1.No
3) Mini Rotary Tablet Machine 6/8 station	1.No
4) Hardness Testers Pfizer, Monsanto, advanced digital	1 each
5) Advanced screw guage digital	1.No
6) Top loading Electronic balance 0.1mg sensitivity	1.No
7) U.V spectrophotometer	1.No
8) Moisture determination apparatus digital	1.No
9) Stability Chambers	2.Nos
10) Deep freezer	1.No
11) Centrifuge digital with 3000-4000 rpm	1.No
12) Digital Micropipettes variable volume 20-200 µl	1.No
13) Digital Micropipettes variable volume 100-1000 µl	1.No
14) High Performance liquid Chromatograph with UV detector and soft ware	1.No
15) Sonicator water bath	1.No
16) Probe Sonicator	1.No
17) Research Microscope with photographic arrangement	1.No
18) Rheometer with software preferably Brooke field	1.No
19) Oven Thermostatic	1.No
20) Refrigerator	1.No
21) Electronic Top loading balance 1 mg sensitivity	1.No
22) PH meter digital	1.No
23) Vacuum Oven	1.No
24) Freeze dryer	optional
25) Spray dryer	optional
26) I.R Press	optional
27) All glass distilled water still	1.No
28) Tensile strength apparatus	1.No (optional
29) Cooling Centrifuge	optional
30) Rotary flash evaporator Buchi/Hidolf	1.No
31) Homogenizer high pressure	1.No
32) Magnetic stirrer cum hot plate with digital display	3.Nos
33) Vortex mixer	1.No
34) Mixer	1.No
35) Aseptic cabinet	optional 1.No
36) Gel electrophoresis	optional 1.No
37) Gel documentation system	optional 1.No
38) Injection pump	optional 1.No
39) Coating pan with speed regulator, hot & cold air& spraying device	1.No
40) Diffusion Cells (Franz/Chin type)	6.No
41) Peristaltic pump	1.No
42) Zeta sizer if both branches are available	1.No
43) Sicve shaker digital with sel of sieves	1.No
44) Tray dryer	1.No

M.Pharm

Pharmaceutical Quality Assurance-Syllabus

I SEMESTER

1. Methods of Drug Analysis
2. Modern Analytical Techniques-I
3. Quality Assurance of Pharmaceuticals
4. Good Manufacturing Practice

PRACTICALS

5.Methods of Drug analysis

6. Quality assurance of pharmaceuticals

1.Methods of Drug Analysis

Unit I

Different methods of analysis; reference standards;method development and validation.

Unit II

An advanced study of the principles involved in the determination of the official compounds in IP with the following analytical techniques

A. Non-aqueous,

B. Complexometric,

C. Oxidation-reduction

D. Diazotization methods

Unit III

An advanced study of the principles involved inthe determination of following organic functional groups:

A. Amines

B. Carbonyl compounds

C. Esters

D. Hydroxyland carboxyl

Unit IV

Principles involved in using the following reagents in pharmaceutical analysis with suitable examples:

A. MBTH(3-methyl-2-benzothizolone hydrazone)

B. F.C Reagent (Folin-Ciocalteau)

C. PDAB (Para Dimethyl Amino Benzaldehyde)

D. 2, 3, 5 - Triphenyl tetrazolium salt

E. 2, 6 - Dichloroquinone Chlorimide

Unit V

Principles involved in quantitative determination of

A. Alkaloids

B. Antibiotics

C. Vitamins

D. Steroids (including cardiac glycosides)

Unit VI

Principles involved in quantitative determination of the following classes of drugs listed in IP

A. Analgesic and Antipyretics

B. Antihypertensives

C. Antihistamines

D. Diuretics

E. Reverse transcriptase inhibitors

REFERENCES

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Pharmaceutical chemistry by Becket and Stenlake
3. Quantitative analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
4. Pharmaceutical Analysis by Higuchi, Bechmman Hassan
5. Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
6. Indian Pharmacopoeia (latest)
7. Instrumental Methods of Chemical Analysis by B.K. Sharma
8. A Text book of Pharmaceutical Analysis by Kerrenth A.Conners
9. Journals (Indian Drugs, IJPS etc.)

Modern Analytical Techniques -I

Unit -I

UV-VISIBLE SPECTROSCOPY : Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules. Choice of solvent and solvent effects. Applications of UV - Visible spectroscopy, Woodward-Fieser rules for calculating absorption maximum, interpretation of spectra, multi-component assay, diifference spectra.

Examples of drugs analysed by this technique.

Unit - II

INFRARED SPECTROPHOTOMETRY : Introduction, basic principles and sampling techniques, interpretation of spectra, applications in pharmacy, FT-IR, Attenuated Total Reflectance (ATR). Near infra red Spectroscopy (NIR) - theory and applications.

Examples of drugs analysed by this technique.

Unit -III

Potentiometry, Conductometry and Fluometry.

Examples of drugs analysed by this technique.

Unit - IV

NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY : Fundamental Principles and Theory, Instrumentation, solvents, chemical shift and factors affecting chemical shift, spin-spin coupling, coupling constant and factors influencing the value of coupling constant, spin-spin decoupling, protonexchange reactions, simplification of complex spectra. FTNMR: interpretation of spectra. C^{13} NMR- Introduction, Natural abundance, C^{13} NMR Spectra and its structural applications.

Examples of drugs analysed by this technique.

Unit -V

MASS SPECTROSCOPY : Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization Mass Spectroscopy (CIMS), Field ionization Mass Spectroscopy (FIMS), Fast Atom Bombardment Mass Spectroscopy (FABMS), Matrix Assisted laser desorption / ionization Mass Spectroscopy (MALDI-MS), interpretation of spectra and applications in Pharmacy.

Examples of drugs analysed by this technique.

Unit - VI

Immunochemical techniques: Immunoelectrophoresis, immunoprecipitation, ELISA, *Radio*immuno assay

Examples of drugs analysed by this technique.

REFERENCE BOOKS :

1. Instrumental methods of analysis- Scoog and West
2. Spectrometric identification of Organic compounds- Silverstein et.al.,
3. Instrumental Methods of Analysis- Willard Dean & Merrit
4. Text book of Inorganic Chemistry- A.I.Vogel.
5. Pharmaceutical Chemistry Vol. I & II- Becket and Stanlake.
6. Pharmaceutical Chemistry Vol. I & II- L.G.Conners
7. Text book of Pharmaceutical Analysis - K. A. Conners
8. Pharmaceutical Analysis- Hiquichi, Bechmann, Hassan.
9. Methods of Drug Analysis - Gearien, Graboski.
10. Pharmaceutical Analysis --Modern Methods -- Part A and B -- Munsen James,W
11. Quantitative analysis of Drugs -- Garrot
12. Quantitative Analysis of Drugs in Pharmaceutical Formulations --P.D.Sethi
13. IP, BP, USP
14. Application of Absorption Spectroscopy of organic compounds --Dyer.
15. Analytical Profiles of Drug Substances --Florey [Volume 13]
16. Spectroscopy of Organic compounds -P.5. Kalsi, Wilely Eastern Ltd, New Delhi.

3. Quality Assurance of Pharmaceuticals

Unit I

Quality of assurance of tablets: Weight variation; test for hardness; friability; chipping, capping; mottling; Test for disintegration and dissolution; Tests for coated and sustained release tablets; sampling techniques; difference in methods if any mentioned in IP,BP,USP and EP.

QA of capsules

Unit II

QA of injectables: sterility testing for pyrogens; particulate matter; volume/weight testing; testing of containers and caps used for packing of injectibles; testing for alkalinity: fibres etc.

Unit III

QA of liquid orals and related formulations:

Unit IV

QA of ointments, creams, gels, lotions, solution for external applications.

Unit V

QA of ophthalmic preparations

Unit VI

QA of metered dosage forms and transdermal implants.

References:

1. Lachman L, Lieberman HA,Kanig JL. The theory and practice of industrial pharmacy.3

ed.,Varghese Publishers, Mumbai 1991.

2. Sinko PJ. Martin's Physical Pharmacy and Pharmaceutical Sciences, 5th edi. B.I. Publications Pvt .Ltd.Noida, 2006.

3. Lachman L, Lieberman HA, Schwartz JB. Pharmaceutical dosage forms : Tablets Vol.1-III, 2 nd ed., CBS Publishers & distributers, New Delhi, 2005.

4. Conners KA., A Text book of Pharmaceutical Analysis Wells JI Pharmaceutical Preformulation : The Physicochemical properties of drug substances. Ellis Horwood Ltd. England, 1998.

5. Yalkowsky SH. Techniques of solubilization of drugs Vol - 12. Marcel Dekker Inc., New York, 1981.

6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah Printer Pvt. Ltd., New Delhi, 2005.

7. Sethi PD., Quantitative analysis of drugs in Pharmaceutical formulations, 3rd de., CBS publications, New Delhi, 2008.

8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS publishers & distributers, New Delhi, 2005.

9. Yoshioka S., Stella VJ. Stability of drugs and dosage forms. Springer (India) Pvt Ltd, New Delhi, 2006.

10. Banker GS, Rhodes CT. Modern Pharmaceutics. 4th ed., Marcel Dekker Inc. New york, 2005.

11. W. Grimm- Stability testing of drug products.

12. Mazzo DJ. International stability testing. Eastern Press Pvt Ltd Bangalore, 1999

13. Beckett AH, Stenlake JB. Practical Pharmaceutical chemistry. Part I & II. 4th ed., CBS publishers & distributers, New Delhi, 2004.

14. IP. Controller of Publication,Delhi. 1996.

15. BP, British Pharmacopoeia Commission office, London, 2008.

16. USP, United States Pharmacopoeial Convention. Inc. USP.

4. GOOD MANUFACTURING PRACTICE (THEORY)

Unit I

Concepts of GMP; Basic Components of GMP: Legal requirements pertaining to GMP:GMP

For manufacturing unit in general.

Unit II

GMP for tablets, capsules, liquid oral manufacturing section.

Unit III

GMP for Parenteral manufacturing section.

Unit IV

GMP for external preparations manufacturing section (ointments, creams, lotions etc.)

Unit V

GMP of section dealing with analysis of various formulations and raw materials.

Unit VI

GMP for stores, packing, and labelling section.

References:

1. Good Manufacturing Practices for Pharmaceuticals. Sidney H, Willig. Drugs and Pharm. Sci. Series. Vol. 109. Marcel Dekker Inc. New York.

2. Good Manufacturing Practices for Pharmaceuticals. Joseph D. Nally. Drugs and Pharm. Sci. Series, Vol.169, Informa healthcare.

3. Modern Pharmaceutics, G.S Banker & C.T. Rhodes, Drugs and Pharma. Sci. Series. Vol,121, Maracel Dekker Inc., New York.

4. How to Practice GMPs, P. P Sharma, Vandana Publication, Delhi.

5. Bulletin of World Health Organization (BLT)

6. (http://www.who.int/bulletin/downloads/en/indexl.html)

7. Remington's Pharmaceutical Sciences, J. P. Remington, Mack Pub. Co., Pennsylvania.

8. Pharmaceutical Packaging Technology, Dean, D.A. Evans, E. R. and Hall, J. H., Taylor and Francis, London.

9. Handbook of Package Engineering by Joseph. F. Handlon.

10. Relevant articles from Journals.

11. Environmental Protection Act 1986.

Methods of Drug Analysis Practical-I:

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.

2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.

3. Simultaneous estimation of combination formulations (minimum of 4 experiments).

a. Vitamins

b. Oral antidiabetics

c. NSAIDs

d. Antimicrobials

e. Antihistamines

f. Antihypertensive etc.

4. Effect of pH and solvent on UV spectrum of certain drugs.

5. Experiments on flame photometry.

6. Use of fluorimeter for analysis of Pharmacopoeial compounds.

7. IR, NMR and Mass spectroscopy - Interpretation of spectra & structural elucidation (atleast for 4 compounds each).

8. Any other relevant exercises basd on theory.

References:

1. Instrumental Methods of Analysis- Scoog and West.
2. Spectrometric Identification of organic Compounds- Silverstein et., al.
3. Instrumental Methods of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry - A. I. Vogel.
5. Pharmaceutical Chemistry Vol.I & II - Becket and Stanlake.
6. Pharmaceutical Chemistry Vol.I & II - L.G. Chatten.
7. Text Book of Pharmaceutical Analysis - K.A. Connors.
8. Pharmaceutical Analysis - Hiquchi, Bechman, Hassan.
9. Methods of Drug Analysis - Gearien, Graboski.
10. Text Book of Biopharmaceutic Analysis - Robert Smith and James Stewart.
11. Pharmaceutical Analysis - Modern Methods- Part A and B - Munson James, W.
12. Quantitative Analysis of Drugs -Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations - P. D. Sethi.
14. IP/ BP/ USP.
15. Application of Absorption Spectroscopy of Organic Compounds - Dyer.
16. Analytical Profiles of Drug Substances - Florey [Volume 13].
17. Spectroscopy of Organic Compounds - P. 5. Kalsi, Wiley Eastern Ltd., New Delhi.

Quality Assurance of Pharmaceuticals Practical - II:

1. Friability testing
2. Hardness testing
3. Disintegration test
4. Dissolution test
5. Test for sterility
6. Test for pyrogens
7. Test for alkalinity of containers
8. Test for rubber/plastic caps
9. Test for allergens
10. Test for particulate matter

References:

1. Lachman L. Lieberman HA, Kanig JL. The theory and Practice of industrial pharmacy, 3rd ed. Varghese Publishers, Mumbai 1991.

2. Sinko PJ, Martin's Physical Pharmacy and Pharmaceutical Sciences 5th ed. B.I. Publications Pvt. Ltd. Noida, 2006.

3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms : tablets Vol I-III, 2nd ed. CBS Publishers & Distributors, New Delhi. 2005.

4. Conners KA. A Text Book of Pharmaceutical Analysis Wells JI.

5. IP/ BP/ USP.

M.Pharm II Semester

Paper I : Modern Analytical Techniques -II

UNIT - I

HPLC and UPLC/UFLC : Principle, instrumentation, column material and sizes; detectors - their scope and limitations ; elution techniques; solvents and solvent mixtures used for elution; use in the analysis of drugs and APIs; LC-MS.

UNIT - II

GAS CHROMATOGRAPHY: Principles, instrumentation, column material; applications; derivatization; GC-MS.

UNIT - III

Other chromatographic techniques: Ion-exchange, ion-pair, affinity, size exclusion, chiral and super critical fluid chromatography: Principle, material used, application in the analysis.

UNIT - IV

Theory, instrumentation and applications of the following thermal methods of analysis: Thermo Gravimetric Analysis (TGA) ; Differential thermal analysis (DTA) ; Differential scanning calorimetry (DSC); and Thermo mechanical analysis (TMA).

UNIT - V

ELECTROPHORESIS: Theory and principle, classification, instrumentation, material, capillary electrophoresis , moving boundary eletrophoresis, isoelectric focussing (IEF); applications

UNIT - VI

Principle and applications of the following techniques in the analysis of Drugs and APIs :

1. Flame photometry
2. Polarimetry
3. Scanning Electron Microscopy
4. Transmission Electron Microscopy
5. Zeta Meter
6. Powder X-ray diffraction

Recommended books:

1. Skoog DA, Holler FJ, Crouch SR, Principles of instrumental analysis, 6th ed. Baba Barkha Nath Printers, Haryana, 2007.

2. Silverstein RM, Webstar FX, Spectrometric identification of organic compounds. 6th ed. John Wiley & sons (Asia) Pvt Ltd., Singapore,2005.

3. Willard HR, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & distributers, New Delhi, 1986.

4. Ewing GW, Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985.

5. Schirmer RE. Modern methods of Pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.

6. Whoston C. X-ray methods, John Wiley & Sons, New York, 1987.

7. Lee DC, Webb M. Pharmaceutical Analysis, Blackwell publishing, Australia, 2004.

8. Gurdeep R. Chatwal, Instrumental Methods of Chemical analysis, Himalaya Publishing House, 2006.

Paper-II: Quality Assurance of Pharmaceuticals-II

Unit-I

Quality assurance of: Large volume parenterals (transfusion fluids etc)

Unit-II

Quality Assurance of biological Products: Biological assays of the following.

1. Vaccines: diphtheria, tetanus, rabies.
2. Enzymes: streptokinase, urokinase.
3. Antitoxins: diphtheria, tetanus.
4. Hormones: chronic gonadotropin, oxytoxin, insulin.
5. Monoclonal antibodies

Unit-III

Quality assurance of Antibiotics: Raw materials (APIs) and formulations.

Unit-IV

Quality assurance of:

1. Guazes (medicated and non-medicated), plasters, cotton
2. Containers and packing materials, caps and labels.

Unit - V

Quality control of Cosmeceuticals: Hair care products (shampoo and hair dyes), baby care products (oils, creams, powders and shampoos), personal hygiene products (shaving creams, after shave lotions and soaps), eye care products (eye shadows, eye liners, and eye brow pencils)

Unit -VI: Quality control of Herbal products: WHO guidelines for the quality control of raw materials used in herbal formulations. Quality control of crude drugs : proximate analysis, including ash and extractive values, crude fiber content, UV and fluorescence analysis of powdered drugs, quantitative microscopy and micro-chemical tests. Analysis of official formulations derived from crude drugs including some herbal preparations, alkaloids (ephedrine, reserpine and ergotamine).

Recommended books:

1. Commercial's manual on drugs & cosmetics, 2nd ed., Commercial Law Publishers (India) Pvt. Ltd, New Delhi, 2004.

2. Sharma PP, Cosmetics-formulation, Manufacturing and quality control, 3rd ed., Vandana Publications Pvt. Ltd., Delhi, 2005

3. Kokare CR. Pharmaceutical microbiology and biotechnology. 2nd ed., Nirali Prakashan, Pune, 2006.

4. Nanda S, Nanda A, KharRK. Cosmetic technology. Birla Publications Pvt. Ltd, Delhi, 2007.

5. Mukherjee PK, Quality control of herbal drugs : an approach to evaluation of botanical. Business horizons New Delhi, 2007.

6. Evans WC, Trease and Evans Pharmacognosy. 15th ed., Saunders, China, 2004.

7. Lachman L, Lieberman HA, Kanig JI. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Bombay, 1991.

8. Remington: The science and practice of pharmacy, 21st ed., vol. I & II, Lippincott Williams & Wilkings, Noida, 2006.

9. Agarwal SS, Paridhavi M. Herbal drug technology. Universities Press (India) Pvt. Ltd, Hyderabad, 2007.

10. Nelson DL, Cox MM. Lehninger Principles of biochemistry, 4th ed., Replika Press Pvt. Ltd, India, 2006.

11. Murray RK, Granner DK, Rodwell VW, Harper's Illustrated biochemistry, 27th ed., McGraw-Hill, New Delhi, 2006.

12. David Pearson. The chemical analysis of foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.

13. Nielson S, Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974.

Paper-III: Drug Regulatory Affairs

Unit-I:

1. Drug regulatory bodies in India, United States and European Union- Organization, structure, activities and responsibilities- An overview.

2. A study of compendia- An overview and a coparative picture of IP, BP, USP, EP.

3. Manufacture for sale or for distribution of drugs other than homeopathic medicines: Applications - for drugs in schedules C and C (1) and other than those specified in these schedules; conditions for issuing licenses; loan licenses; inspection; cancellation of licenses; special provisions relating to biological and other special products.

Unit-II:

Schedule M and rules connected with it (The new schedule M):

Part 1: Good manufacturing practices and requirements of premises, plant and equipment.

Part 1A: Specific requirements for manufacture of sterile products, parenterals preparations small volume injectables and large volume parenterals) and sterile ophthalmic preparations.

Part 1B: Specific requirements for manufacture of oral solid dosage forms (Tablets and Capsules).

Part 1C: Specific requirements for manufacture of oral liquids (Syrups, Elixirs, Emulsions and Suspensions).

Part 1D: Specific requirements for manufacture of topical products ie., external preparations (Creams, Ointments, Pastes, Emulsions, Lotions, Solutions, Dusting powders and identical products).

Part 1E: Specific requirements of premises, plant and materials for manufacture of active pharmaceutical ingredients (bulk drugs).

Unit - III:

1. Schedule M II: Requirements of factory premises for manufacture of cosmetics:

a) General requirements b) Requirement of plant and equipment c) Standards for cosmetics.

2. Schedule M III: Requirement of factory premises for manufacture of medical devices.

3. Provisions related to biological and other special products- Part X of D & C act

4. Labelling and packing of drugs other than homeopathic medicines- Part IX of D & C act

5. Standards for surgical dressings- Rule 124C and scheduleF2; methods of test

6. Standards for ophthalmic preparations-Rule 126A and schedule FF.

7. Particulars to be shown in manufacturing records-Schedule U and rules associated with it.

Unit IV:

A study of:

1.Narcotic drugs and psychotropic substances act 1985.

2.Medical and toiletry preparations (the excise duties) act 1955 and rules 1976.

3.Pollution and environment control act.

Unit V:

1. Requirements and guidelines on clinical trials for import and manufacture of new drugs- Schedule Y. Appendices associated with the schedule.
2. GLP and cGLP, principles (OECD guidelines of GLP)

Unit VI

1. ICH guidelines for stability testing.
2. WHO guidelines- an overview.
3. USFDA and other certifying agencies.

Recommended books:

1. Drugs and Cosmetics act, rules and its amendments published by Govt. of India.
2. Forensic pharmacy, BS Kuchekar, AM Khadatare and SC Jitkar, 6th ed., Nirali Prakashan.
3. Textbook of Forensic pharmacy, BM Mittal, 9th ed., Vallabh Prakashan.
4. Drugs and Cosmetics act, 1940, SW Deshpande.
5. Law and Drugs, Law publications- SN Katju
6. Law of Drugs in India, Hussain.
7. Narcotic drugs and psychotropic sunstances act 1985.
8. Medicinal and toilet preparations (the excise duties) act 1955 and rules 1976.
9. Pollution and environment control act.

Paper- IV: Pharmaceutical Process Validation

UNIT-I

Introduction to pharmaceutical validation; definition; manufacturing process model; scope of validation; advantage of validation; organization for validation; validation master plan; types of process validation; prospective; concurrent; retrospective and revalidation. design qualification; installation qualification; operational qualification

And performances qualification of facilities.

UNIT-II

Process validation of dosage forms like tablets, capsules, liquid orals, transdermal preparations and equipment- dry powder mixers, tablet compression machine, fluidized bed dryer, dry heat heat sterilization tunnels, capsule filling machines, dissolution test apparatus.

UNIT-III

Process validation of parental formulations and sterile dosage forms: Validation of aseptic areas, processes and instruments- autoclave, filling machine.

UNIT-IV

General principles of analytical method validation; Need for validation of analytical methods; Validation of analytical instruments and methods-UV-VIS spectrophotometer, IR spectrometer, HPLC/UPLC, LC-MS.

UNIT-V

Utilities and cleaning validation: validation of pharmaceutical water system and pure steam; validation of HAVC system and air handling units; cleaning of equipment and cleaning of facilities, validation of computer systems.

UNIT-VI

A study of the following topics:

1. Validation of coating process
2. Validation of medical devices like stents, intra uterine devices, implants.
3. Change control and SUPAC.

Recommended books:

1. Pharmaceutical process validation, Ira. R. Berry & robert Nash, 2nd Ed., Marcel Dekker Inc.

2. Validation of Pharmaceutical process (Sterile products), F.J. Carleton and J.P. Agalloco, 2nd Ed. (Revised and Expanded), Marcel Dekker Inc.

3. Pharmaceutical Quality Assurance, M.A. Potda, Niali Prakashan, Pune.

4. Current Good Manufacturing Practices, M.A . Potda, Pharma-Med press, Hyderabad.

Practical-I: Quality Assurance of Pharmaceuticals-II

1. HPLC/ UPLC analysis of drugs in formulations
2. GC- and GC-MS analysis of drugs/ APIs
3. Capillary electrophoresis
4. Chiral separations
5. Gel electrophoresis
6. Experiments based on thermal methods of analysis
7. Flame photometric analysis
8. Polarimetry
9. Refractive index determination
10. Experiments based on TLC and Paper chromatography
11. Bioassays

Practical-II: Pharmaceutical Process Validation

1. Validation of analytical method (minimum of four exercises)
2. Validation of following equipment
    a. Autoclave
    b. Hot air oven
    c. Dry powder mixer
    d. Tablet compression machine
3. Validation of processing area
4. Validation of atleast two analytical instruments- HPLC, UV-Vs Spectrophotometer
5. Cleaning Validation of one equipment
6. Validation of sterile areas and sterilization methods- Aseptic filling area and membrane filtration.
7. Validation of laminar air flow unit
8. Validation of dissolution test apparatus.