M.PHARMACY (PHARMACEUTICS), Ist SEMESTER
1.1 T : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS
ASSIGNMENT TOPICS

1. Chromophores and their interaction with Electromagneticj radiation. Absorption spectra of organic compounds and complexes and its utilization in qualitative and quantative analysis of drugs.
2. Qualitative interpretation of I.R-Spectra and Applications of I.R.-Spectroscopy.
3. Radio immuno assay
4. Fragmentation and Interpretation in Mass spectrometry.
5. Recent advances in Mass spectroscopy.
6. Applications of Mass spectrometry in the analysis of drugs.
7. Applications of Gas chromatography in pharmaceutical analysis of drugs.
8. Applications of HPLC.
9. Interpretation of X-Ray powder diffraction data.
10. Method development in HPLC

M.PHARMACY (PHARMACEUTICS), Ist SEMESTER

1.1 T : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS

SEMINAR TOPICS

1. U.V-Visible spectroscopy.
2. I.R.-Spectroscopy.
3. Principle, Instrumentation and Concept of chemical shifts in NMR-spectroscopy.
4. Masds spectrometry
5. Gas Chromatography.
6. HPLC.
7. HPTLC.
8. Principle and Applications of X-Ray diffraction method.
9. DTA and DSC.
10. Principle, methods and Applications of different Radio immuno assay.

I[st] SESSIONAL SYLLABUS

1.1 T : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS

1. **UV-VISUAL SPECTROSCOPY :** Brief review of electromagnetic spectrum, UV-Visual range, energy-wavelength-color relationship. Interaction of electromagnetic radiation (UV-Vis) and matter and its effects. Chromophores and their interaction with Electromagnetic Radiation. Absorption spectra of organic compounds and complexes illustrating the phenomenor and its utilization in qualitative and quantitative analysis of drugs. Shifts and their Interpretation (including solvent effects)

2. **INFRA-RED SPECTROSCOPY :** Nature of Intra-red radiation. Interaction of LR. Radiat ion with organic molecules and effects on bonds. Brief outline of classical I.R. instrumentation and the interpretation of spectra, including sample preparation for spectroscopy. Qualitative interpretation of I.R. spectra. Quantitative methods useful in drug analysis.

3. **MASS SPECTROMETRY :** Basic principles and brief outline of instrumentation. Ion formation and types, molecular ion, meta stable ions, fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristics peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization mass spectrometry, GC-MS other recent advances in MS, FAST ATOM BOMBARDMENT MASS spectroscopy. Application of mass spectrometry in the analysis of drug.

4. **RADIO IMMUNO ASSAY METHODS :**

IInd SESSIONAL SYLLABUS

1.1 T : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS

1. **NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY :** Fundamental principles of NMR (Magnetic Properties of nuclei, applied field and procession; absorption and transition frequency). Chemical shifts concept; Isotopic nuclei, Reference standards; proton Maganetic spectra, their characteristics, presentation, terms used in describing spectra and their interpretation (Signal no. Position, intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomena in high resolution PMR Spin spin coupling. Application of Signal Sprit and coupling constant data to interpretation of spectra. Decoupling and shift reagent methods.

   Brief outline of principles of FT-NMR with reference to 13 CNMR; Spin-spin and spin-lattice relaxation phenomena. Free induction decay (FID) proton noise decoupling signal averaging time domain and frequency domain signals nuclear overhauser enhancement; CNMR spectra, their presentation, characteristics, interpretation examples and application in drug analysis.

2. **GAS CHROMATOGRAPHY :** Instrumentation packed and open tubular column, column efficiency parameters, the Van Deemeter equation, Resolution, liquid stationary phases, Derivatisation methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; FID, ECD, TCD, NPD. A critical comparison of sensitivity, selectivity and field of application of these detectors. Examples of GC applications in Pharmaceutical Analysis.

3. **LIQUID CHROMATOGRAPHY :** Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and microbore columns, normal and reversed-phase packing materials, Reverse-phases HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC; refractive index, Photometric and electrochemical. Comparison of sensitivity, selectivity and field of applications of these detectors. HPTLC-instrumentation and applications.

4. **X-RAY DIFFRACTION AND DSC, DTA METHODS :** Introduction, Generation of X-Rays, Elementary crystallography; miller Indices, X-ray, diffraction Bragg's law, X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data. Applications of XRD, DSC and DTA in the characterization of Pharmaceutical solids.

1.1 P : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS
LIST OF EXPERIMENTS

01. Estimation of Gatifloxacin by UV-Spectrophotometry

02. Estimation of Paracetamol by UV-Spectrophotometry

03. Estimation of Sulpha methaxazole by Visible Spectrophotometry

04. Estimation of Salbutamol Sulphate by Visible Spectrophotometry

05. Estimation of Riboflavin by Visible Spectrophotometry

06. Determination of Moisture content by Karl Fischer Aparattus / Potentiometry

07. Determination of Sodium by Flame Photometry

08. Determination of Potassium by Flame Photometry.

09. Interpretation of I.R.Spectra

10. Interpretation of Mass Spectra

M.PHARMACY (PHARMACEUTICS), 1ST SEMESTER
1.2. T. ADVANCED PHYSICAL PHARMACEUTICS
ASSIGNMENT TOPICS

1. How do you carry out phase solubility study of a newly discovered drug ? Collect information about the various types of phase solubility diagrams.
2. How do you formulate emulsions by HLB method? Collect a list of surfactants with their usual Concentration, HLB values and purpose.
3. Prepare a list of drugs that exist in different polymorphic state and give their applications in pharmacy (At least 50 drugs to be collected)
4. Instrumentation of tablet machines
5. Prepare a list of polymers used in pharmacy with their chemical name, structure, solubility parameter and its use.
6. Explain thermodynamics of diffusion, and explain in detail about diffusion principles in biological systems.
7. Emphasizes a detail note on diffusion kinetic and related expressions.
8. Explain the principle and procedures of diffusion studies carried out for different dosage forms.
9. Prepare a list of drugs that undergo degradation by oxidation, reduction, hydrolysis and light. Give the possible preventive measure.
10. Various approaches to achieve sink conditions in dissolution rate testing.

M.PHARMACY (PHARMACEUTICS), 1ST SEMESTER

1.2.T ADVANCED PHYSICAL PHARMACEUTICS

SEMINAR TOPICS

1. Ternary Phase diagrams and their applications.
2. Adsorption, wetting and crystal growth in suspensions.
3. Crystal properties.
4. Physics of tablet compaction.
5. Polymer science.
6. Dissolution rate testing methodology for modified release dosage forms.
7. Principles of diffusion.
8. *In vitro – In vivo* correlation.
9. Accelerated Stability testing.
10. Viscometers.

Ist SESSIONAL SYLLABUS
1.2 T : ADVANCED PHYSICAL PHARMACEUTICS

1. Theory of solubilisation and solubilisation techniques; Solubility and solubilisation of non electrolytes, solubilisation by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation.

2. **Diffusion and Dissolution :** Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, thermodynamics of diffusion. Dissolution : Basic theories of dissolution, dissolution models. Sink conditions in dissolution and its importance. In vitro and in vivo correlations.

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

4. **Rheology :** Theoretical consideration, instrumentation, rheological properties of disperse systems and semi-solids.

IInd SESSIONAL SYLLABUS
1.2 T : ADVANCED PHYSICAL PHARMACEUTICS

1. **Theories of Dispersion : Solid liquid dispersion :** Adsorption, wetting, crystal growth mechanisms and prevention of crystal growth.
   Emulsions : Formation and stability of emulsion with special emphasis of electrical theory, HLB theory and die-electric propereties. Preparation, evaluation and applications of multiple and microemulsionhs.

2. **Solid state Properties :** Crystal properties and polymorphism techniques for study of crystal properties; solid state stability, flow properties of powders, segregation, and its importance.

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

4. **Polymer Science :** Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state. Application of polymers in Pharmaceutical formulations.

M.PHARMACY (PHARMACEUTICS), 1ST SEMESTER
1.2.P. ADVANCED PHYSICAL PHARMACEUTICS
LIST OF EXPERIMENTS

1. Study the effect of beta cyclodextrin on the solubility of salicylic acid and construct phase solubility curve.
2. Construct Acetone / water /C_6H_6 ternary phase diagram.
3. Formulate and prepare multiple emulsion of liquid paraffin.
4. Determine the effect of talc on flow properties of lactose granules.
5. Study the effect of binder concentration on compaction.
6. Study the effect of lubricant on compaction.
7. Development of dissolution medium for a model drug.
8. Study the effect of surfactants on solubility of the drug.
9. Carry out dissolution testing of the drug by non sink and sink conditions.
10. Determine the order and rate constant associated with decomposition of NaoH- phenolphthalein pink color complex.
11. Accelerated stability testing – data problems.
12. Determine the order and rate contrast associated with decomposition of ethyl acetate.
13. Determine the effect of temperature on viscosity of water and calculate the constant A and E_v from modified Arrhenius equation.
14. Construct the thixotropic rheogram for sodium CMC dispersion using rotational viscometer.

M.PHARMACY (PHARMACEUTICS), 1ST SEMESTER
1.3. T. DRUG REGULATORY AFFAIRS
ASSIGNMENT TOPICS

1. Elucidate about Preformulation Studies on controlled release dosage forms conforming to regulatory specifications of United States Regulatory Body.
2. Explain the guidelines for packing materials and their evaluation tests complying with regulatory requirements as per Indian Drug Regulatory authorities.
3. Enunciate the regulatory requirement in design of stability testing of NCE (New Chemical Entity), Active Pharmaceutical Ingredients (API) in final packing as per European Community Regulatory authorities.
4. Describe the Current Guidelines and Developments to conduct the bioavailability studies with special mention on documentation and statistical analysis as per Indian Drug Regulatory authorities.
5. Draw a note on guidelines for approval of International aspects of Excipients by all territories.
6. Mention the Regulatory guidelines for clinical study design, documentation, presentation and interpretation as per United States Drug Regulatory authorities.
7. Explain about Clinical Trails.
8. Emphasize the role of Statistical Analysis of clinical data and factorial designs.
9. Explain about Intellectual Property Rights in the context of International and Indian scenario.
10. Detail about ICH guidelines specified by regulatory authorities for residual solvents in pharmaceuticals.

M.PHARMACY (PHARMACEUTICS), 1ST SEMESTER

1.3. T. DRUG REGULATORY AFFAIRS

SEMINAR TOPICS

1. Preformulation Studies on sterile dosage forms conforming to regulatory specifications of United States Regulatory Body.
2. USFDA regulatory guidelines for formulation and manufacturing process.
3. Analytical method validation
4. Testing parameters for storage and stability as per United State regulatory authority.
5. Current Guidelines for bioavailability study as per United States Drug Regulatory authorities.
6. Clinical study design as per European community regulatory authorities.
7. Intellectual property rights
8. Evaluation tests of packing materials as per closures United States Drug Regulatory authorities.
9. Preformulation Studies on semi solid forms conforming to regulatory specifications of Indian Regulatory Body.
10. ICH guidelines for extension of shelf – life of dosage forms.

I[st] SESSIONAL SYLLABUS

1.3. T. DRUG REGULATORY AFFAIRS

1. **Manufacturing :** Regulatory requirements as per European community, united states and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastomer test, microbiological test and evaluation of closures.

2. **Stability Testing :** Scientific and technical background to the design of stability testing regulatory requirements as per European community, united states and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of self-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines Analytical method validation, pharmacokinetic and toxicokinetic validation.

3. **Preclinical Aspects of Biopharmaceutics :** Current guidelines and developments as per regulatory requirements of European communityk united states and Indian regulatory authorities in respect of clinical bioavailability, study, design, presentation, documentation and statistical analysis.

4. **Intellectual Property Rights :** Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United states and Indian regulatory authorities, documentation, presentation and application.

IInd SESSIONAL SYLLABUS
1.3.T. DRUG REGULATORY AFFAIRS

1. **Formulation Development :** Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities.

2. **Biopharmaceutics :** Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

3. **Clinical Pharmacology and Pharmacodynamics :** Regulatory guidelines as per European community, united states and Indian regulatory authorities on Clinical study design, documentation, presentation and interpretation.

   Clinical Trials : Definition, phase I, phase II, Phase III and Phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

I/II M.PHARMACY - Ist SESSIONAL EXAMINATIONS
Time : 10.00 am to 11.00 am

S.No.	Date	Subject
01	02-01-2009	Advanced Instrumental Methods of Analysis
02	04-01-2009	Advanced Physical Pharmaceutics
03	06-01-2009	Drug Regulatory Affairs

II/II M.PHARMACY - IInd SESSIONAL EXAMINATIONS
Time : 10.00 am to 11.00 am

S.No.	Date	Subject
01	23-03-2009	Advanced Instrumental Methods of Analysis
02	25-03-2009	Advanced Physical Pharmaceutics
03	27-03-2009	Drug Regulatory Affairs