MPY- 201Pca- ADVANCED PHARMACEUTICAL ANALYSIS –I
(Instrumental and Modern Pharmaceutical Analysis)

1. Separation method : Theory, instrumentation and applications.
   i. Supercritical fluid chromatography and extraction
   ii. Sizre exclusion chromatography
   iii. Ultra performance liquid chromatography
   iv. Solid phase micro extraction
   v. High performance thin layer chromatography

2. Quantitative optical spectroscopic method:Theory, instrumentation and applications.
   i. Atomic absorption spectroscopic
   ii. Inductive coupled plasma atomic emission spectroscopy
   iii. Inductive coupled plasma mass spectroscopy
   iv. Chemilumience
   v. Laser
   vi. Photo aquatic spectroscopy
   vii. Raman spectroscopy
   viii. Optical rotary dispersion

3. Recent advancement in instrumentation and applications if IR, Mass and NMR with special refernce to FT-IR, GC-MS, LC-MS,FT-NMR, 2D-NMR, LC-NMR, C-13NMR.Interpretation of IR- NMR and Mass spectra and their empirical correlation with chemical structure .
4. Solid state analysis
   Introduction, analytical methodsto study molecular, particulars and bulk properties, with special reference to TEM, SEM and Particle size analyzer.

Reference books:

1. Munson J.W., **Pharmaceutical Analysis Modern Method part – A**
2. Munson J.W., **Pharmaceutical Analysis Modern Method part –** B
3. Wagner H, Bladt, S., **Plant Drug Analysis**
4. Frank A. Settle, **handbook of Instrumental Techniques for Analytical Chemistry.**
5. Satinder Ahuja and Stephen Scypinski, **handbook of Modern Pharmaceutical Analysis.**
6. Mitchell D. Ericson**, Analytical Chemistry of PCB's.**

MPY- 202 Pca ADVANCED PHARMACEUTICAL ANALYSIS –II
(Quality Control and Quality Assurance of Pharmaceutical)

1. Analytical method validation: Analytical method validation parameter, Procedure, Cleaning validation, instrumental validation, and personnel validation.
2. Identification and quantitation determination of preservative and antioxidant, emulsifiers, stablizers in pharmaceutical formulation.
3. Quality controls of containers, closers, caps for pharmaceutical preparation as per I.P.
4. Quality control of cosmetics products:hair care production, skin care product, colour cosmetics, body care products, ethnic products, hair setting lotion, eye shadows.
5. General method of quality control of tablets, capsule and liquid dosage forms, parentral preparation, ointments and creams, suppositories and controlled release products.
6. BIOSTATISTICS: Introduction and significance validation of analytical method normal distribution, degree of freedom, measures of variation standard deviation, variance standard error, tests for statistical significance-student T test, chi-square test, correlation of variance and precision accuracy, regression and correlation for linear and curve system, method of collection of data, graphical representation of data, mean, mode, median and standard deviation, confidence level, null hypothesis, analysis of variance, theory of probability, combination and reaches percentage and proportion and statistical different between proportion. Analysis of variance, two ways ANOVA and multiple comparison procedure.

Reference books:

1. **Indian Pharmacopoeia**
2. **United State Pharmacopoeia**
3. **ICH Guidelines.**
4. Bolton, S. **Pharmaceutical Statistics.**
5. Carle Tiori**, Validation of Aseptic Pharmaceutical Process.**
6. **OPPI, Quality Assurance.**
7. **Lachman, Theory and Practice of Industrial pharmacy**

MPY- 203Pca ADVANCED PHARMACEUTICAL ANALYSIS –III
(Biological, Microbiological and Phytopharmaceutical Analysis)

1. Pharmacological method of standardization :
   i. Bioassay of pharmacopoeial drugs, methods used in the bioassay of hormones. Vitamins, cardiac drugs and other pharmacopoeial Preparations.
   ii. Bioassay methods of autocoids
   iii. Development of new Bioassay methods for drugs and biochemical samples.
   iv. Biochemical methods of estimating various physiological constants of the body.
   v. Determination of LD50 acute toxicity.

2. Microbiological methods of analysis:
   i. Microbiological screening methods for antimicrobial activity, plate method and serial dilution technique.
   ii. Microbiological assay- assay of vitamins and antibiotics with special reference to drugs official in Indian pharmacopoeia.
   iii. Bioassay of some vaccines and antitoxins.
   iv. Biological assay for-
      a. Living contaminant in vaccine
      b. Histamine like substance.
      c. Heamolysines
      d. Heparin, amylase, hyluronidase

3. Analysis of Nutraceutical:

   i. General method of analysis of major chemical constituents like protein, vitamins. Carbohydrate and fat.
   ii. Dtermination of physical constant, moisture, solids, crude fibre.

4. Analysis of Phytopharmaceuticals:
   i. Method of systematic phytochemical analysis including extraction and identification of plant constituents using chromatographic techniques.
   ii. Quality control of crude drugs: mono and polyherbal formulation by F.M.O. determination, LOD proximate analysis including ash and extractive values phytomorphology, crude fibre content, U.V. and florescence analysis of powdered drugs.
   iii. Analysis of official formulation derived from crude drugs including some ayurvedic preparation.
   iv. WHO guidelines, regulatory requirements and patent laws for quality control of raw materials used in herbal formulations. Standardization parameter protocol development for herbal products.

Reference books:

1. Wagner H, Bladt **S. Plant Drug Analysis.**
2. Barton J. Wright**, Microbiology Assays.**
3. J.H. Burn, D.J.Fonney, S.L.G. Goodwin**, Biological Standardization.**
4. D.R. Laurence, P.N. bernett, M.J. Boren**, Clinical Pharmacology**
5. Indian pharmacopoeia**.**
6. N.Gerhard Vogel**, drug Discovery and evaluation.**

MPY- 204Pca - ADVANCED PHARMACEUTICAL ANALYSIS –IV
(Applications and Regulatory Guideline for Pharmaceuticals)

1. immunoassay – general principle, heterogeneous and homogenous immuno system. Production of immunoassay reagent. Immunoassay method evaluation.
2. Sample preparation and handling : types of samples, sample preparation, extraction, post extraction derivatization, dilution and matrix matching for solid, semi solid and liquid organic and inorganic samples.
3. A detailed study of various principles and procedure involved in quanlitative and quantitative analysis of pharmaceutical preparations using the following reagent and reaction.
   i. oxidative coupling reaction using MBTH (3-methyl-2-benzothiazolinone hydrazone hydrochloride)
   ii. Diazotiazation followed by coupling
   iii. Oxidation followed by complexion
   iv. Oxidation followed by charge transfer reaction
   v. Condensation reaction using the reagents, p-dimethyl amino benzaldehyde (PDAB), p-dimethyl amino cinnamaldehyde (PDAC), foilns reagent and Gibbs reagent, folin ciocalthechu reagent.
4. Good Laboratory Practice: overview and regulatory guidelines for GLP
5. An overview of kinetic concept. Stability prediction and calculation protocol. Regulatory requirement, experimental design and interpretation of data for Degradation and impurity analysis of pharmaceutical drug candidate and dosage forms as per ICH and USFDA guidelines.
6. Bioanalytical method development for pharmaceutical drug candidate and dosage forms as per ICH and USFDA guidelines and their application to clinical studies.

Reference books:

1. **Indian Phaarmacopoeia**
2. **ICH Guidelines.**
3. **USFDA guidelines**
4. Cartensem, Drug stability, principles and practices.
5. Convors. Amiden and Stella, **Chemical Stability of Pharmaceuticals.**
6. Wagner**, Principles of Clinical Pharmacokinetics.**
7. Rowland and Tozer**, Clinical Pharmacokinetics**.
8. Ritschel. **Handbook of basic Pharmacokinetics**.
9. Gibaldi, **Biopharmaceutics and clinical Pharmaceutics.**
10. Frank A. Settle, **Handbook of Instrumental techniques for Analytical chemistry.**