I/II M.PHARMACY (2nd SEMESTER)

2.1.T ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES AND SPECIAL ANALYTICAL REAGENTS IN PHARMACEUTICAL ANALYSIS

Part - I :

Theory, instrumentation and applications of the following **Special Techniques** in Analuysis :

a) Super Fluid Critical Chromatography

b) Gel permeation Chromatography

c) Affinity Chromatography

d) Electrophoresis

Part - II :

Principles and procedures involved in using the following **Chromogenic reagents** in Pharmaceutical Analysis :

a) Folin-Ciocalteu reagent (FC reagent)

b) 3-Methyl-2-Benzothiazolinone hydrazone hydrochloride (MBTH) reagent

c) P-N-Methylamino phenol Sulphate (Metol)

d) N-1-Naphthyl Ethylenediamine dihydrochloride (Bratton-Marshell agents)

e) Emmerie-Engel reagent

f) P-dimethylaminobenzaldehyde (PDBA) and P-dimethylaminocinnamaldehyde (PDAC)

g) 1, 2-Naphthaquinone-4-sulfonate sodium (NQS)

h) 2, 4, 6-tripyridyl-S-triazine (TPTZ)

i) Dyes (for extractive spectrophotometry)

j) Ninhydrin reagent

I/II M.PHARMACY (2nd SEMESTER)

2.1.P ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES AND SPECIAL ANALYTICAL REAGENTS IN PHARMACEUTICAL ANALYSIS

PRACTICALS : BASED ON THEORY

RECOMMENDED BOOKS & JOURNALS :

1. Instrumental Methods of Analysis, Willard, Dean and Merrit et al
2. A Text book of pharmaceutical Analysis (Vols. 1 & 2) - Roger E Schnmor
3. Methods of Drug Analysis - Gaerian & Grbowski
4. A Text Book of Pharmaceutical Analysis - K A Connors
5. Practical Pharmaceutical Chemistry (Vols. 1 & 2) - Beckette & Stenlake.
6. Pharmaceutical Analysis - P.Parimoo
7. Pharmaceutical Analysis - Kodern Methods by J W Munson (Marcel Decker)
8. Indian Drugs (Journal Published by IDMA)
9. Journal of Industrial and Scientific and Inddustrial Research (Journal Published by CSIR)
10. Journal of Pharmaceutical and Biomedical Analysis
11. Analysis (International Journal)
12. Analyst (International Journal)
13. Pharma Zie (International Journal)

I/II M.PHARMACY (2nd SEMESTER)

2.2.T QUALITY ASSURANCE & QUALITY CONTROL (QA & QC)

1. Concepts and Philosophy of TQM, GLP, SOP, ICH, ISO-9000
2. Organization and Personnel responsibilities, training, hygiene and records.
3. In process quality controls on various dosage forms (sterile and non sterile)
4. Packaging and Labeling Controls :
   Line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners; film wrapper; Blister packs, Bubble packs, shrink handling; foil/plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; Quality control of packaging material and filling equipment.
5. Warehousing and Good warchousing practices
6. Distribution and Distribution of records, Handling of returned goods, Recovered materials and Reprocessing.
7. Complaints and Recalls, Evaluation of complaints, Recall procedures, Related records and documents.
8. Regulatory aspects of Pharmaceuticals and Bulk drug Manufacturing, Regulation of drugs and pharmaceuticals.
9. Certification and licensing procedures, WHO and NABL certification accreditation.
10. Stability testing of formulation and shelf life prediction.

2.2.P QUALITY ASSURANCE & QUALITY CONTROL (QA & QC)

PRACTICALS : BASED ON THEORY

REFERENCES :

1. Quality assurance and quality management in pharmaceutical industry - Y.Anjaneyulu (Pharma Book Syndicate)
2. Quality Assurance Guide - Vol. 1 & 2, Organization of Pharmaceutical Products of India.

I/II M.PHARMACY (2nd SEMESTER)

2.3.T VALIDATION AND DOCUMENTATION

1. Validation methods of
   a) Equipment
   b) Processing Techniques including mixing, granulation, drying compression, filtration and filling.
   c) Methods of equipment for dry heat sterilization, autoclaving and membrane filtration.
   d) Air handling equipment and facilities in zones
   e) Water supply systems, de-ionized and distilled water and water for injection.
2. Calibration of Analytical Instruments - Validation of Systems and validation of analytical procedures (as per ICH and Pharmacopoeia)
3. Sampling techniques, collection and classification of data, common tendency, precision and accuracy, probability theory, correlation and regression, Test for significance, t-test, F-test, chi-square test and analysis of variance (ANOVA)
4. Data Generation and Storage
5. Finished products release, Quality Review, Quality audits, Batch release and documentation.

RECOMMENDED BOOKS FOR 2.2 T AND 2.3 T

1. Quality Assurance of pharmaceuticals (A compendium of guidelines and selected materials (Vol. 1 & 2, Pharma Book Syndicate, Book street, Hyderabad)
2. Basic tests for pharmaceutical substances by WHO (1988, 1991)
3. A guide to total quality management - K.Mitra and SK Ghosh
4. Good manufacturing practice (GMP) - Mehra
5. How to practice GMP - PP Sharrma
6. ISO 9000 and total Quality Management - SK Ghosh.
7. Packaging drugs and Pharmaceuticals - WA Jenkins & KR Osborn
8. The drug and cosmetic Act, 1940 - Vijay Malik
9. European Pharmacopoeia (Vol. 1 to 4)
10. Analytical validation iii & tech, Ching Chang Chaw.