CHEM714 - Pharmaceutical Analysis

The objective of this course is to provide an overview of instrumental techniques used in analysis of different pharmaceutical compounds and formulated drug products. Many physical and chemically different attributes of analytes and drug products are encountered in pharmaceutical analysis. The guiding analytical test method parameters are key to controlled and meaningful analysis in different sample matrices.

Inclusive to the analytical techniques is the documentation and compliance requirements of the regulatory agencies which will be addressed as a component of the overall analytical process. It will not be possible to cover the whole spectrum of analytical techniques that are used in the pharmaceutical industry and the focus of this class will be on instrumentation such as chromatography and different types of spectroscopy.

Lecture: Fall 2013, 6:00PM – 9:00PM, Thursdays, Kupf 105

Suggested Text Books:

1. Principles of Instrumental Analysis by D. Skoog. Pub: Thomson Brooks/Cole

2. (Optional) Method Validation in Pharmaceutical Analysis - A Guide to Best Practice, Ed.: J. Ermer, J.H.M. Miller, Pub.: Wiley-VCH, ISBN: 3-527-31255-2

Topics to be Covered

Introduction to Pharmaceutical Analysis
Chromatography Fundamentals
HPLC/Gas Chromatography and Detection
Fundamentals of UV/Vis Spectroscopy
Dissolution Apparatus and Testing
Physical Pharmaceutical Testing
Laboratory cGMP Controls
Instrument Qualifications
Development Process – IND/IMPD/NDA/ANDA
Analytical Methods Validation
Pharmacopeia
Pharmaceutical Stability Testing

Grading System: 40% for Midterm Exam
40% for the Final Exam
20% Student presentations/Paper