SARDAR PATEL UNIVERSITY
MASTER IN PHARMACY (M. PHARM.)
FIRST SEMESTER
MPH-503: ANALYTICAL METHOD VALIDATION

THEORY: (3 hours per week)

1. GLP- Basic concept of Q.A, Sampling and Operating characteristic curves, Sampling plans, Statistical procedures of assay development, Data generation and storage, Q.C.documentation, Retention samples, Records, audit of quality Control Facilities.

2. Validation of Instruments and their calibration : UV, IR, HPLC and Dissolution test apparatus, HPTLC

3. Validation of Analytical method: Analytical method validation requirement Validation parameters, Accuracy, Precision, Biases, Ruggedness, Statistical design and Statistical consideration.

4. Current good manufacturing practices

5. Guidelines and Techniques for experiments on animals.

6. Regulatory consideration in validation.


BOOKS RECOMMENDED:

1. Analytical Method Development and Validation- Swartz, Michael. Marcel Decker
2. Analytical Method Development and Validation — Ira S. Kmll, Michael Swartz. CRC.
3. Laboratory Systems Validation Testing and Practice- Paul Coombers
6. The Quantitative Analysis of Drugs - D.C. Garratt
7. Understanding ISO 9000 and Implementing the Basics to Quality—D.H.Stamatis, Marcel Decker
8. ISO 14000 — B. Othery and ISO 9000—Gower