PHARMACEUTICS-VI (PHARMACEUTICAL QUALITY MANAGEMENT)

Course Outline

(Theory) Paper 5

1. INTRODUCTION:

Basic concepts and introduction of pharmaceutical industry in relevance to quality control departments, Testing, Quality Management System, Quality Assurance, Good Manufacturing Practices and Current Good Manufacturing Practices. General understanding of good laboratory practices and validation.

2. QUALITY CONTROL OF SOLID DOSAGE FORMS (conventional and modified release dosage forms):

(a) Physical tests: Hardness, Thickness, Diameter, Friability, Disintegration, Weight Variation.

(b) Chemical tests: Content uniformity, Assay of active Ingredient.

3. QUALITY CONTROL OF SYRUPS, ELIXIRS, AND DISPERSE SYSTEM: Viscosity, its determination and application in the Quality Control of Pharmaceuticals, Weight per ml and Assay of active Ingredient.

4. QUALITY CONTROL OF SUPPOSITORIES: Dissolution test, Uniformity of weight, Assay of active Ingredient, Liquefaction time test and Breaking test.

5. QUALITY CONTROL OF STERILE PRODUCTS (PARENTERALS): Sterility Test and Sterile section management, Leaker's test, Clarity test, Pyrogen test for Parenteral and other sterile preparations, Assay for active Ingredient.

6. BIOLOGICAL ASSAYS: Biological methods, Standard preparations and units of activity, Bioassay of antibiotics, Bioassay of insulin injection, Assay of prepared digitalis and Assay of Vitamin D.

7. ALCOHOL DETERMINATION: Alcoholometric methods, Problem during distillation of alcohol, Method for liquids containing less than 30% or more than 30% alcohol and special treatment before distillation.

8. ALKALOIDAL DRUG ASSAY: Weighing for assay, Extraction of drugs, Maceration, Percolation, Continuous extraction, Purification of Alkaloids and determination of alkaloids.

9. QUALITY ASSURANCE OF VACCINES: Introduction, Quality measures for stability of vaccines, potency testing, and post market surveillance of vaccines.

10. MISCELLANEOUS DETERMINATIONS AND TESTS: Determination of weight/ml, Water/Moisture content, Loss on Drying, Evaluation of Ointments, Ash contents and Alkalinity of Glass.

11. STANDARDIZATION OF PHARMACEUTICALS: An understanding of quality assurance system adopted in pharmaceutical industry. Good Manufacturing Practices and Current Good Manufacturing Practices.

12. STATISTICAL INTERPRETATION OF QUALITY CONTROL CHARTS DURING MANUFACTURING PROCESSES:

PHARMACEUTICS-VI (PHARMACEUTICAL QUALITY MANAGEMENT) (Practical)
Paper 9 Marks 100 NOTE: Practical of the subject shall be designed from time to time on the basis of the above mentioned theoretical topics and availability of the facilities e.g. Assay of various spirits, tinctures, extracts, syrups and elixirs, Assay of Ointments and suppositories,

Assay of tablets and capsules, Test for alkalinity of glass, Determination of alcohol contents in the Pharmaceutical preparations and Pyrogen test. Sterility test, Determination of Ash contents, Determination of Moisture contents, Determination of total solids, Determination of viscosity of syrups, gels etc. Determination of emulsion types (Note: A minimum of 20 practicals will be performed).

Recommended Books

1. A H Beckett and J B Stennlake, **Practical Pharmaceutical Chemistry**, Part-I and II. The Alton Press, London.
2. A M Knevel and F E Digangi, **Jenkin's Quantitative Pharmaceutical Chemistry**, McGraw-Hill Book Company, New York.
3. K A Connors, **A Text Book of Pharmaceutical Analysis**, John-Wiley and Sons, New York.

4. A Braithwaite and F J Smith, **Chromatographic Methods**, Chapman and Hall, London.
5. G D Christian, **Analytical Chemistry**, John Wiley and Sons, New York.
6. Karamt A Javaid, **Pharmaceutical Quality Assurance in Class, Industry and Market,** Aziz Publishers, Lahore-Pakistan (1993).
7. Gil Bismuth and Shosh Neumann, **Cleaning Validation, A practical approach**. CRC Press, LLC, USA, 2003.
8. J T Carstersen and C T Rhodes, **Drug Stability: Principles and Practices,** 3rd edition (revised and expanded) Mercel Dekker, New York. 2000.
9. Sydney H Willig, **Good Manufacturing Practices for Pharmaceuticals.** Marcel Dekker Publishing.
10. Bryant R, **The pharmaceutical Quality Control Hand Book**, Aster Publishing Corporation, Eugene, 1989.
11. Braun R E, **Introduction to Instrumental Analysis**, McGraw-Hill Book Co, NY, 1987.