69-DRUG QUALITY CONTROL I

Aims

To introduce the students to the subject of quality control of pharmaceuticals and the physical, chemical, physicochemical and biological tests and assays used for their assessment.

To establish understanding of laboratory techniques for some of the major branches of pharmaceutical sciences.

To instruct the student on the preparation of laboratory reports, using appropriate statistical and mathematical calculations.

Learning Outcomes

On successful completion of this unit should be, at threshold level,

Demonstrate an understanding of methods employed for the quality controls of pharmaceuticals.

Perform experiments in the laboratory using the most up-to-date techniques for drug stability.

Carry out a given set of laboratory instructions, record and manipulate numerical data and to present this information in an appropriate format.

Syllabus outline

Introduction to quality control of pharmaceuticals. Methods of analysis (physical and physicochemical methods). Pharmaceutical technical procedures. Biological tests and assays. Pharmaceutical stability.

Laboratory practical: Decomposition of phenobarbital and salicylic acid in alkaline environment (orders of reactions, Arrhenius equation, activation energy). Quality control assays of tablets containing ampicillin and prednisolone (dissolution studies, analysis of drug content and weight uniformity).

Learning and Teaching Strategy

The unit will be delivered through a combination of formal lectures and laboratory classes. All laboratory reports will require statistical, computing and mathematical skills. The material is covered by a textbook and a lab note.

Assessment

Four (4) laboratory reports will be submitted within 2 weeks after the final laboratory class and will require analysis and interpretation of experimental data. A successful completion of the unit will be demonstrated by a final written examination at the end of the semester (grade ≥5).

Indicative Reading

1. Physical Pharmacy Fourth Edition, Ed. Al. Martin Lea & Febiger Philaddelphia, London 1993.
2. Pharmaceutics – the Science of Dosage Form Design, 2nd Edition, Churchill Livingstone, London 2002.

Drug Stability: Principles and practices Ed. C. T. Rodes and J.O. Cartensen,