A QUALITATIVE STUDY OF THE DIFFERENT BRANDS OF PARACETAMOL TABLETS IN THE KENYAN MARKET

A research project submitted to Mount Kenya University for the award of a Bachelors Degree in Pharmacy

Mount Kenya University

MAUREEN WANJIRU K

BPHARM/09/04324

2013

ABSTRACT

Paracetamol or chemically named p-acetyl-N-aminophenol is an OTC drug being extensively used as an antipyretic and an analgesic.

During this research simple approaches were followed i.e. the British Pharmacopoeia and USP and other standard book's standards and procedures to evaluate the quality parameters of 15 different brands of paracetamol 500mg by selecting samples of different batches (3 batches of each), manufactured in industrial zones of Kenya . Types of quality tests performed are weight variation, disintegration time, dissolution, hardness and friability.

This research advocated for the need of constant market surveillance to ascertain their compliance with official standards and equivalence to the innovator products. The aspect of this study was to assess the various brands and to determine their adherence to stringent guidelines of the quality standards. The need for quality assurance is high in the industry as medicines, health supplements and other products have a direct effect on an ailing or a fit body. A qualitative analysis was used to ascertain the quantity of drug release of a drug from a solid dosage form and therefore assesses the biavailability. Disintegration test involved the determination of the prescribed time the tablets were to break into particles under a given set of conditions. This was through the use of a disintegration tester. The mechanical strengths were determined by the likelihood of a tablet to break fracture during handling. This research was carried out in Mount Kenya University Pharmaceutics Laboratory during the period of February to November 2013. These tests were carried out under physiological conditions for dissolution and disintegration as this allowed assessment according to the in-vitro performance of the product. The hardness and friability tests were carried out in the room conditions. The disintegration, hardness and dissolution tests on the tablets all complied with official specifications. However, most of these tablets failed the friability test. Following the findings in this research, the samples used showed a lot of variation from the specifications in their performance and this necessitates the need for quality assurance and control during manufacture of the tablets. There is also the need for constant market surveillance to ascertain their compliance with official standards and equivalence to the innovator products.