

**TO QUALITATIVELY AND QUANTITATIVELY DETERMINE
THE LABEL CLAIM OF VARIOUS AMOXICILLIN BRANDS IN
THE MARKET BY USING HIGH PERFORMANCE LIQUID
CHROMATOGRAPHY ASSAY METHOD BY COMPARISON
WITH STANDARD AMOXICILLIN USP**

KARIUKI ANDREW KARIUKI

BPH /101/00029

**A Research Project submitted in partial fulfillment of the requirements for
the award of Bachelor of Pharmacy of Mount Kenya University.**

OCTOBER 2013

ABSTRACT

Amoxicillin have become first line medicine on the essential medicines list for the treatment of infections caused by micro-organisms. The purpose of carrying out this project was to determine the label claim of various amoxicillin brands of 500mgs from sampled manufactures in Kenyan market using high performance liquid chromatography assay method and comparing them with standard amoxicillin USP. There are recently published arguments suggesting all generic antibiotic drugs do not present the full reliability needed to claim therapeutic equivalence with branded drugs. The problem is especially crucial for generic intravenous drugs, which do not need any bioequivalence study before they can be marketed. All generic drugs are not equivalent and they normally differ in their, levels of impurity, pharmacokinetics, pharmacodynamic relationship, in vitro effectiveness, therapeutic effectiveness in experimental models, etc. So that finally, the specifications approved in the initial submission file of a brand name drugs are not always respected by a generic drug. Available data on clinical effectiveness is excessively rare. Even if most of this information needs to be verified, it seems necessary to review regulations for marketing authorization of generic antibiotic drugs. Random research design was used in drug collection. The products collected were derived from sampled manufactures within Kenyan market. This research was carried out as a case study within Thika District which is located 50km from the city of Kenya. The analysis was carried out at the Mount Kenya University. This project was done within a period of five months.