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Kamore, Anthony, Kihono.

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Assessment of the quality of paracetamol tablets in the Kenyan market

A research project submitted to Mount Kenya University in partial
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By: Anthony Kihono Kamore
BPH/09/00007

Supervisor: Dr. Alex Kigundu Muriithi

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ABSTRACT

Paracetamol is a derivative of para – aminophenol. It is used as an analgesic and antipyretic. It has weak anti-inflammatory activity. The purpose of this study is to show the need for conducting post marketing quality surveillance for drugs registered in Kenya so as to ensure that only products of high quality are marketed. This was done by checking two fundamental quality attribute for the tablet dosage form which are the uniformity of weight and content of the active ingredient. For the uniformity of content, the method used was a USP 2007 method where high performance liquid chromatography was used. Paracetamol in the test samples was detected by an ultra violet detector and integrated to produce chromatograms. The test results showed that one brand out of the ten brands studied failed the assay criteria of 90-110% of the label claim. Two batches marginally passed the assay criteria at 90%, two others at 91% and non by more than 95%. There was a significant variation in the uniformity of weight since two batches had a RSD>2%, five batches with a RSD>1% and two products with a RSD<1%. The findings suggest that there are serious flaws in the manufacturing procedures adopted for the manufacture of these tablets. Therefore, post marketing surveillance is important in passing judgment about the quality of the different brand of pharmaceutical products in the market. The post marketing surveillance is particularly important for potent drugs with narrow therapeutic window and for poorly soluble poorly permeable drugs that are likely to have bio-availability problems, in addition to antibiotics to reduce risk to drug resistance.