

**POST-MARKET QUALITY OF RIFAMPICIN CONTAINING FIXED-DOSE
COMBINATIONS OF ANTI-TUBERCULOSIS DRUGS IN KAMPALA, UGANDA**

BY

OCAN MOSES (BSc, MUK)

SUPERVISORS

Associate Prof. Celestino Obua (MD, MSc, PhD)

Prof. Jasper Ogwal-Okeng (MB chB, MSc, PhD)

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ABSTRACT

Background

Tuberculosis (TB) is an important curable infectious disease in Uganda; its treatment however is facing a challenge of increasing drug resistance. Although Rifampicin containing Fixed-Dose Combination (R-FDC) drugs are a mainstay in TB treatment, about 1/5 are reportedly substandard in the global drug market.

Objective

To determine the post-market quality of R-FDC anti-TB drugs in Kampala, Uganda.

Method

Eight private and five public pharmacies in Kampala were randomly selected, and the drug samples purchased or obtained as gifts respectively. Drug quality was assessed using visual inspection, weight uniformity, dissolution, and HPLC drug assay.

Results

This study shows that 33.3% of R-FDC anti-TB drugs analyzed for drug assay contain rifampicin content outside the recommended compendial limits of 90-110% (U.S.P). Six batches of R-FDC anti-TB drugs were easily purchased without prescription from private pharmacies of Kampala city. This study found that 42.9% of the samples analyzed were not found in the National human drug register. All the drug samples passed visual/physical inspection and weight uniformity tests with all the samples having less than 5.0% relative standard deviation. All the FDC samples tested for rifampicin dissolution passed the test with all releasing more than 80.0% of rifampicin into solution in 45 minutes.

Conclusion

Rifampicin containing FDC anti-TB drugs whose rifampicin content does not conform to the recommended pharmacopoeial standards exist in Kampala city, Uganda drug market.