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Quality and *In vitro* Equivalence Testing of Chloroquine Phosphate 250 mg USP Tablets in Sri Lanka

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Exceptionally high quoted unit prices of antimalarials and the non-availability of World Health Organization (WHO) pre-qualified registered suppliers were two main challenges in procuring antimalarials in Sri Lanka. As such, having bioequivalence/ biowaiver studies to ensure the therapeutic performance of generics is of paramount importance since they can reduce the annual health expenditure associated. The objective of this study was to ensure the interchangeability of the generic chloroquine tablets produced locally by the State Pharmaceutical Manufacturing Corporation (SPMC) with a WHO prequalified product. Chloroquine is classified as eligible for biowaiver by the WHO based on its Biopharmaceutical Classification (BCS). Randomly selected three batches of generic tablets manufactured by SPMC and a batch of prequalified Chloroquine phosphate 250 mg from Anti-Malarial Campaign (AMC) Sri Lanka were tested for quality and comparative dissolutions according to the United States Pharmacopeia (USP) specifications. All four batches passed the weight variation, friability, disintegration, dissolution, and assay as per the specifications of USP, but the hardness test was passed only by the WHO prequalified product. In the comparison of dissolution test results, the locally produced generic product showed the highest standard of quality plus invitro equivalence that supported biowaiver conditions. The study confirmed that the SPMC chloroquine is of good quality and is equivalent to the reference product and hence interchangeable with the current Chloroquine Phosphate tablets used by the AMC.

Keywords*: chloroquine phosphate, quality assessment, biowaiver*