MULTI-TRANSFER OF GENERIC ANALYTICAL METHODS TO
COMBAT POOR QUALITY ANTIMALARIAL MEDICINES: A
LABORATORY BASED APPROACH TO SUPPORT DRUG QA/QC
SYSTEMS

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Poor quality medicines (counterfeit/falsified, sub-standard and degraded) constitute a harmful
threat to the public health, particularly in under-resourced countries [1, 2]. Hence, there is a real
need to develop fast, efficient, simple and transferable analytical methods applicable for the
quality control (QC) of medicines in these countries, reinforcing the role of protecting the
population health.

In this context, generic and separative methods are required to assess the integrity of drugs. So, a
robust LC method applicable to 19 antimalarial medicines was developed in Belgium through
Design of Experiments (DoE) and Design Space (DS) optimization strategies [3]. These
approaches permitted to gain knowledge on the method, which in turn, were employed to
develop a procedure meeting specific needs of Rwanda in terms of evaluating the quality of
antimalarial medicines included in the official document [4]. Thus, this method was specifically
developed and improved for the analysis of 8 antimalarial Active Pharmaceutical Ingredients
(APIs) and 4 major excipients.

Initially developed on a Waters LC system in Belgium, this method was successfully transferred
to 3 different LC systems in Rwanda namely Shimadzu, Cecil and Agilent, emphasizing the
interest of robust methods developed through a DoE-DS strategy. Rapid, reliable and
reproducible chromatographic results were obtained with these LC systems, with respect to
peaks retention times. In order to give more guarantees to the Rwandan health authorities as well
as other health organizations, further transfers, i.e. geometric ones were realized taking into
account several combinations of antimalarial medicines as well as the pharmaceutical
formulations. Prior to their use to QC of medicines sampled in specific and targeted areas of
Rwanda, the methods were validated using the total error strategy [5]. Very interesting and
surprising results were obtained in terms of falsification detection particularly in the Rwandan
fragile areas such as boundaries.

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References

2) Newton P.N et al., PLOS Medicine, December 06, 2011, DOI: 10.1371