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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