

Low-Cost Analytical Device for Detecting Counterfeits and Sub-Standards in Emerging Countries

J. Schappler¹, E. A. Diop¹, E. Reginato¹, C. Rohrbasser², P. Bonnabry¹, S. Rudaz¹

¹ School of Pharmaceutical Sciences, University of Geneva, University of Lausanne, 1205 Geneva , Switzerland

² Pharmelp (<http://pharmelp.ch/>), Fribourg, Switzerland

Introduction: The fight against counterfeit medicines is complex and different levels of action are necessary. Among them, the quality control (QC) of imported batches can be achieved, although this strategy is often difficult to apply in developing countries due to (i) the lack of suitable analytical equipment, (ii) the high cost of analytical instruments, maintenance and consumables, and (iii) the low availability of reference substances and consumables.

Aims: A strategy based on multiple injections was validated for the simultaneous identification and quantitation of active principles and was successfully applied to drugs selected from the WHO list of essential medicines.

Methods: In this context, the use of capillary electrophoresis (CE) appears of utmost interest since (i) the separation is achieved in a capillary of reduced dimension (total volume of 1 µL) filled with an aqueous buffered solution, (ii) no organic solvent is needed, and (iii) injection volumes are in the nanoliter range, which enables simple, reliable, and cost-effective drug QC [1]. The University of Geneva collaborated with the University of Applied Sciences of Fribourg and the Geneva Pharmacy Hospitals to build a low-cost CE device and help transitional countries to fight against counterfeit medicines. The instrument was successfully implemented in emerging countries, including Mali, Cambodia, Senegal, Democratic Republic of Congo, and more recently Rwanda and Madagascar. In order to analyze a high number of compounds and benefit from the device with basic chemistry knowledge, simple and generic methods were developed.

Results: This last approach was illustrated by the application on two important active principles (AP), namely metronidazole and amoxicillin. After method validation, this strategy was used for the quality control as well as for the detection of counterfeits in samples coming from Tanzania, thanks to collaboration with Pharmacien sans Frontières (PSF) [2].

Conclusions: This analytical tool and method validation with quantitative analytical robustness and accuracy is a reliable help for the QC of most medicines available in developing countries.

Keywords: Capillary electrophoresis, low cost analytical chemistry, counterfeit medicines, Pharmelp.

References:

- [1] Westenberger BJ et al. Int J Pharm 2005; 306: 56-70.
- [2] Schappler J et al. Spectra Analyse 2014; 298: 63-73