

Title: Low-cost analytical device for counterfeits detection in emerging countries

Abstract:

The proportion of counterfeit medicines has dramatically increased in the last few years. According to numerous official sources, the proportion has reached 80% in African countries. The fight against this calamity is complex and different levels of action are necessary. Among them, the quality control of batches imported into the different countries can be achieved, although this strategy is often difficult to apply due to a lack of suitable analytical equipment in developing countries. Simple, reliable, and cost-efficient drug control approaches are needed and the currently used methods entail numerous drawbacks such as (i) the availability of reference substances, (ii) the maintenance of analytical instruments, and (iii) the availability and costs of consumables. In this context, the use of capillary electrophoresis (CE) appears of utmost interest since the separation is achieved in a capillary of reduced dimension (total volume of 1 μL), filled with an aqueous buffered solution of electrolytes. No organic solvent is needed and injection volumes are in the nanoliter range, which is perfectly adapted to the low availability of reference substances. Another CE feature is the equipment simplicity, with no mechanical constraint and simplified maintenance, only requiring a periodical control of the electrodes and detection performance during routine analyses.

The low-cost CE was successfully implemented in 8 emerging countries (i.e. Mali, Cambodia, Senegal, Republic of Congo, Rwanda, Burkina Faso, Tanzania, and Madagascar) leading to several missions, conventions (e.g. Pharmelp, Pharmaciens sans Frontières), scientific communications (5 articles, 4 oral communications, 5 posters), dissemination (>50 press releases and interviews), and international recognitions (e.g. runner up for the Humanity in Science Award from the Analytical Scientist in 2015). In order to analyze a high number of compounds and benefit from the device with basic chemistry knowledge, we developed simple and generic methods, which were validated according to regulatory guidelines and are currently applied for the simultaneous qualitative and quantitative analysis of more than 80 drugs from the list of the 200 essential medicines defined by the World Health Organisation.

According to the feedback gathered through the missions regarding the instrument, the methods, and the field constraints, a new generation of device is currently under development in collaboration with Prof. H. Girault (EPFL, Sion) and his team. The further steps of the project should include:

- (i) a new/renewable energy source to supply HV regardless of the local electric facilities,
- (ii) a new detection system to broaden the analysis range to any pharmaceutical drug
- (iv) an integrated SW to simplify data treatment and reporting.

Bio:

Serge Rudaz studied pharmacy in Switzerland, where he obtained his PhD in 1997. Later, he joined the National Research Center in Roma (Italy) for a post-doctoral position concerning the application of capillary electrophoresis (CE) hyphenated to mass spectrometry (MS) for chiral separation in biological fluids. From 1998 to 2011, he was master-assistant in Phytochemistry at the University of Lausanne then Maître d'Enseignement et de Recherche (MER), where he developed new strategies for untargeted metabolomic analyses. He was promoted Associate Professor in 2012 in the School of Pharmaceutical Sciences at the University of Geneva where he leads the biomedical and metabolomics analysis (BMA) group.

He has so far contributed to the field of analytical sciences with diverse activities including invited lectures, invited professorship in various Universities (Lyon, Pavia, etc.). He is a member of various scientific societies and scientific boards, such as the "Chimiométrie" congress series. Research group leader and member of the management Board of the Swiss Centre for Applied Human Toxicology (SCAHT) Foundation, Serge Rudaz is also president of the Competence Center in Chemical and Toxicological Analysis (ccCTA) and vice-president of the French Association of Separation Sciences (AFSEP).

He published numerous scientific papers (>240) or book chapters (>10). Currently, he is interested in (UHP)LC and CE coupled to MS, advances in sample preparation, analysis of pharmaceuticals and counterfeit medicines, biological matrices, clinical and preclinical studies, including metabolism and toxicological analysis. Serge Rudaz is an expert in various chemometric approaches, including experimental design (DOE) validation and regulation (ISO17025) as well as multivariate data analysis (MVA) for metabolomics.

Web: <https://epgl.unige.ch/labs/fanal/analyses-biomedicales>