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Counterfeits and Sub-Standards medicines: Five years experience in Senegal with CE

E.A. Diop[1, 2], S.O. Sarr[2], J. Schappler[1], S. Roth[3], O. Vorlet[3], D. Rhème[3], C. Rohrbasser[4], P. Bonnabry[1,4], S. Rudaz[1,4]

[1]School of Pharmaceutical Sciences, University of Geneva, University of Lausanne – Geneva – Switzerland
[2]Faculty of medicine and Pharmacy, University Cheikh Anta Diop of Dakar(UCAD), Senegal
[3]College of Engineering and Architecture of Fribourg, CH-1705 Fribourg, Switzerland
[4]Pharmelp – Fribourg – Switzerland

ElHadji.Diop@unige.ch

The situation

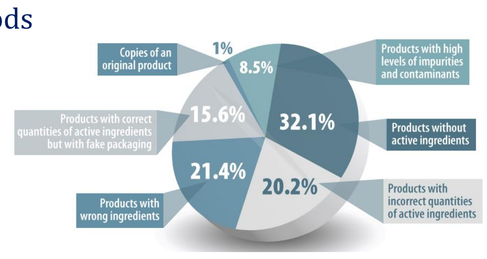
The fight against **counterfeit medicines** is complex and different levels of action are necessary.

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.

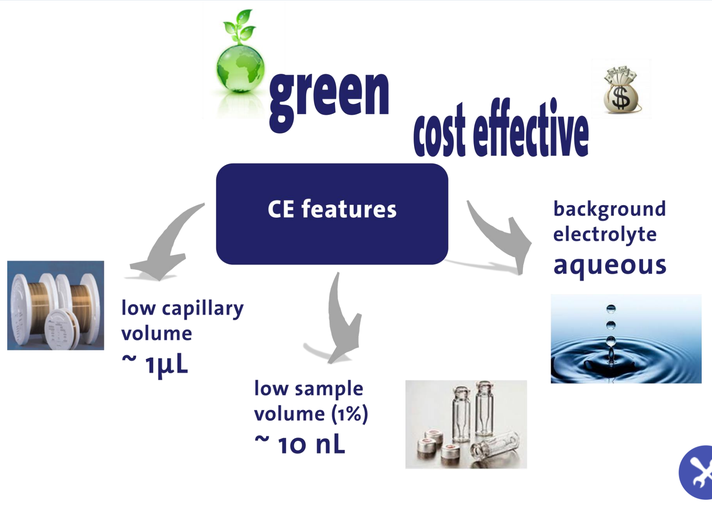
Simple, reliable, and cost-efficient drug control approaches are needed and the currently used methods entail numerous drawbacks such as:

- the availability of reference substances
- the maintenance of analytical instruments
- the availability and costs of consumables

who.int

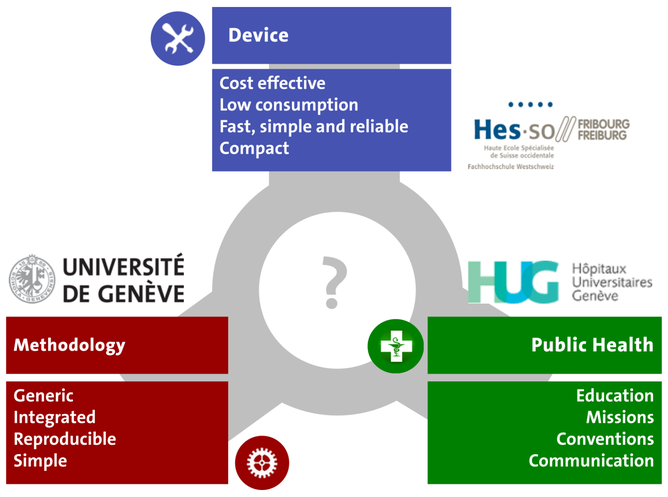


The analytical strategy



The use of **capillary electrophoresis (CE)** is particularly appropriate for cost-effective drug control since no organic solvent is needed and injection volumes are in the nanoliter range, which is perfectly adapted to the low availability of reference substances.

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(ECB)** and help transitional countries to fight against counterfeit medicines.



The implementation in Senegal

A first ECB device was brought to **Senegal in 2012** where the laboratory staff was trained to use the instrument, implement the methods, perform the quality control of drug material and drug product. Three PhD theses and two master work were done with this technique. Another CE-apparatus was brought in 2016.

Training on ECB by Pharmelp in 2012

Demo on WynCE® in 2016

The methods

To analyze various compounds and benefit from the device with basic chemistry knowledge, **simple methods** were developed. The methods were validated for selected active ingredient principles and successfully applied to drugs from the **WHO list of essential medicines.**

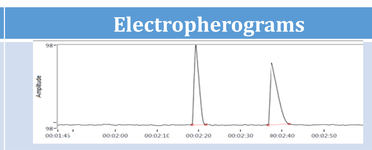
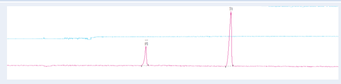
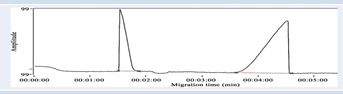
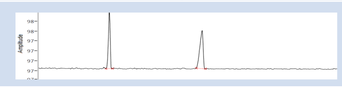
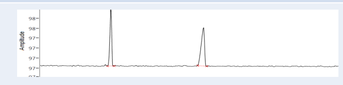
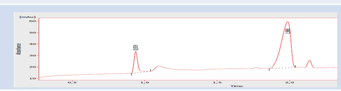
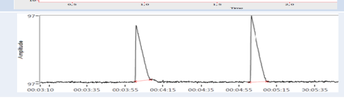
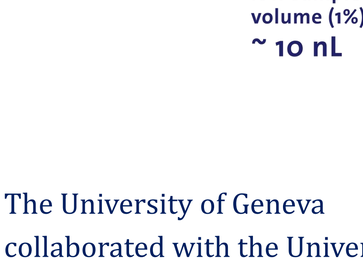
API	Method characteristics	Electropherograms
Trimethoprim	Duration:3 min, IS: procaine BGE : Phosphate, pH 6.1 Voltage:20 kV	
Diclofenac	Duration:3 min , IS: benzoic acid BGE : Borate, pH 9.0 Voltage:20 kV	
Metronidazole	Duration: 5min , IS :procaine BGE :phosphate, pH 2,5 Voltage: 20kV	
Chlorphenamin maleate	Duration:5min , IS: diclofenac BGE: Phosphate, pH 2.5 Voltage: 20kV	
Phenobarbital	Duration:5 min , IS: furosemide BGE: Borate pH 6.1 Voltage: 20 kV	
Furosemide	Duration:5 min ,IS: phenobarbital BGE : Borate , pH 6.1 Voltage: 20kV	
Captopril	Duration: 3 min ,IS: chlorpheniramin BGE : Borate, pH 9.0 Voltage: 20kV	
Quinine	Duration: 5 min, IS: procaine BGE: phosphate, pH 2,5 Voltage:20kV	

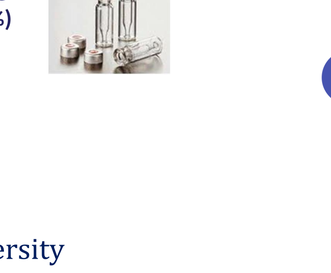
Table 1: Methods applied for QC of drugs

The low-cost device | ECB

injection

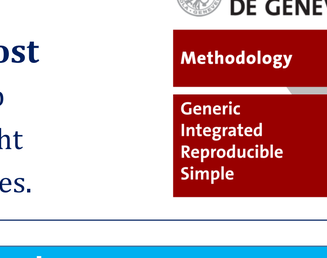


pressure



voltage

detection



software

design

pharmelp

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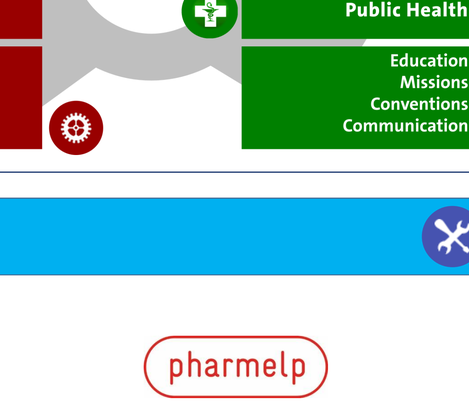

The results

Over the 5 years more than 200 samples were collected and analyzed with CE

- The analyzes revealed 17% (2/12) of overdosage for quinine and 64% (7/11) of overdosage for samples containing phenobarbital.
- 25%(2/8) captopril samples were sub-standards
- Trimethoprim-sulfamethoxazole combination: 100% conformity .
- 29 samples including 18 of amoxicillin and 11 of metronidazole. 100% conformity was obtained for all API assayed
- Diclofenac: 100% conformity
- Paracetamol: 100% conformity

Most results were confirmed by HPLC

CE implementation

Due to its **short analysis time, simple instrumentation, low sample and solvent consumption as well as reduced operating costs**, this analytical strategy proved to be adapted to:

- evaluate the quality of drugs
- establish the presence of the active principle(s)
- quantify the amount of the active principle(s)
- **Reduction of maintenance needs and improvement of instrumentation robustness**
- The impact of the CE in the analytical lab at UCAD was great for education and quality control of drugs

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