

Accepted Manuscript

Title: Raman chemical imaging for spectroscopic screening and direct quantification of falsified drugs

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PII: S0731-7085(17)32009-5
DOI: <https://doi.org/10.1016/j.jpba.2017.10.005>
Reference: PBA 11536

To appear in: *Journal of Pharmaceutical and Biomedical Analysis*

Received date: 6-8-2017
Revised date: 6-10-2017
Accepted date: 9-10-2017

Please cite this article as: Hervé Rebiere, Maxime Martin, Céline Ghyselinck, Pierre-Antoine Bonnet, Charlotte Brenier, Raman chemical imaging for spectroscopic screening and direct quantification of falsified drugs, *Journal of Pharmaceutical and Biomedical Analysis* <https://doi.org/10.1016/j.jpba.2017.10.005>

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Raman chemical imaging for spectroscopic screening and direct quantification of falsified drugs

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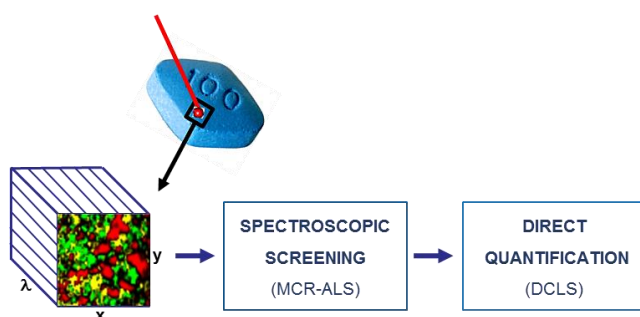
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GRAPHICAL ABSTRACT



ABSTRACT

Falsified drugs are a threat to the health of patients. The analytical control of such products contributes to the fight against this global issue. Raman chemical imaging is a method that relies on consecutive measurements at the surface of a sample, combining spectroscopy, microscopy and chemometrics. This article explores the capabilities of this analytical technique proposing an innovative methodology with spectroscopic screening for the identification of chemical compounds and the direct quantification of the active substance (without prior calibration). Two chemometric methods were used: *Multivariate Curve Analysis – Alternate Least Squares* for the qualitative analysis and *Direct Classical Least Squares* for the quantitative analysis. The methodology was optimized with samples prepared in the laboratory and validation parameters were studied. The methodology was then applied to real (authentic and falsified) samples of Viagra[®] and Plavix[®]. Despite the presence of fluorescence emission in some samples, the methodology succeeded in the detection of active pharmaceutical ingredients, and in the discrimination of three salts of clopidogrel (in generic formulations of Plavix[®]). The quantitative deviation from the reference method ranged from -15% to +24% of the active substance content. This deviation may be considered to be acceptable since it is sufficient for assessing the risk to the health of patients and for quickly alerting the health authorities.

Keywords: Raman, Chemical imaging, chemometrics, falsification, counterfeit, direct quantification

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