

Highlights of Analytical Chemistry in Switzerland

Division of Analytical Chemistry

A Division of the Swiss Chemical Society

NIR Spectroscopy to Identify Counterfeit Drugs

Simon Meyer*

*Correspondence: S. Meyer, Swissmedic, Labor OMCL Pharmazeutika, Hallerstrasse 7, Postfach, CH-3000 Bern 9, Tel.: +41 31 322 02 67, Fax: +41 31 322 05 04, E-mail: simon.meyer@swissmedic.ch

Keywords: Counterfeit medicines · NIR spectroscopy

Spam mails advertising prescription drugs for a discount price are well known to all of us. They may be just a minor irritant, but behind these mails a billion dollar market is hiding.

Counterfeit drugs present a substantial health risk. WHO estimates that about 50% of drugs ordered at non-licensed online pharmacies are counterfeit. However, to date no counterfeit drugs have been observed in the legal supply chain in Switzerland.

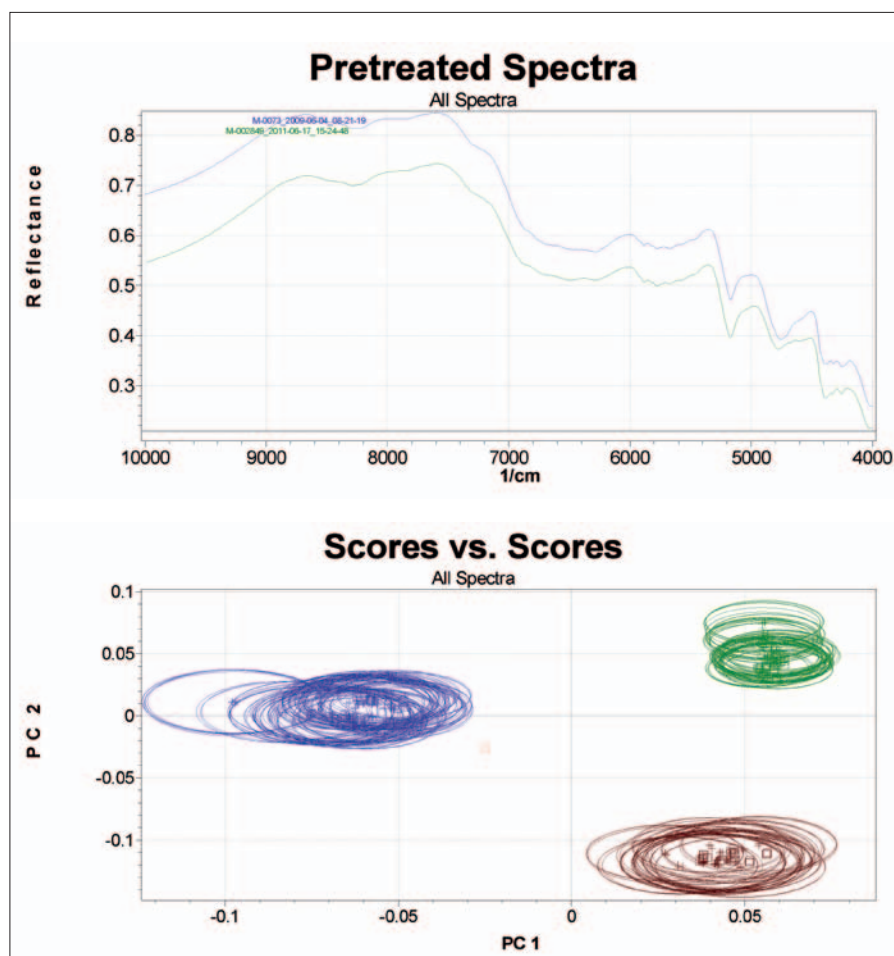
In 2010, Swissmedic (the Swiss Agency for Therapeutic Products) received more than 500 confiscated samples for further analysis from the Swiss Federal Customs. Due to the steadily

increasing number of samples, new methods for rapid identification are needed. One promising approach is near infrared (NIR) spectroscopy. The high penetration depth (several millimetres) of the NIR-radiation into the surface allows for a non-destructive and extremely fast analysis. A full spectrum scan (800–2500 nm) can be acquired in less than 10 seconds.

The broad and overlapping signals in NIR spectroscopy preclude a direct interpretation of the spectra. Therefore, a chemometric model (calibration) has to be established based on data of different genuine lots. Based on statistical models, the collected data is pretreated (*e.g.* derivatives or normalisation algorithms) to eliminate spectral effects. In a second step a principal component analysis (PCA) is performed in order to reduce the data quantity to the significant differences between the samples. After validation, the chemometric model can be used to distinguish between authentic and counterfeit medical products.

The evaluation of these data showed that NIR spectroscopy is capable to rapidly and reliably distinguish between authentic and counterfeit drugs.

Received: September 8, 2011



Counterfeit (left) and authentic (right) drug.

Top: Similar NIR spectra of genuine (blue) and counterfeit (green) drugs for erectile dysfunction (ED). Bottom: Chemometric modelling (PCA) is used to distinguish the counterfeited drug. Cluster calibration of three authentic medicines for ED treatment. The red square in the middle corresponds to the green spectrum in the top figure.

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Please contact: Dr. Veronika R. Meyer, EMPA St.Gallen, Lerchenfeldstrasse 5, 9014 St.Gallen
Phone: +41 58 765 77 87, Fax: +41 58 765 77 62, Mail to: veronika.meyer@empa.ch