Determination of Counterfeit Drugs

Counterfeit drugs are a substantial and growing problem, both in the developed and in the developing world.

The legal definition of “counterfeit drug” varies by country, but one useful definition of that is that of the World Health Organization, which “defines a counterfeit pharmaceutical product as a product that is deliberately and fraudulently mislabeled with respect to identity and/or source.”

Counterfeit drugs represent a two-fold danger to the public. On the one hand, counterfeits that do not contain the proper active ingredient in the proper quantity result in the patient’s condition going untreated. On the other hand, counterfeits may contain toxic materials that result in the patient being poisoned. In both cases, the patient has been the victim of fraud, and the confidence that the public places in the health-care system is undermined.

Determining whether a suspect product is genuine or counterfeit is often done with wet-chemical procedures, such as thin-layer chromatography. Accurate and reliable performance of these techniques requires skilled personnel and the appropriate laboratory facilities. Furthermore, these methods often cannot be performed as rapidly as would be desired.

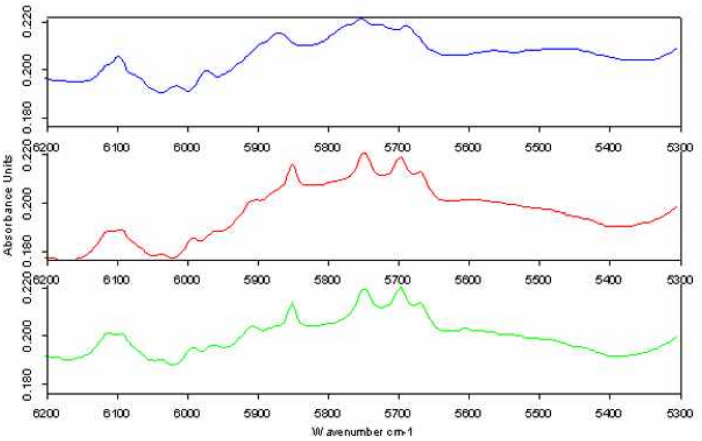

Figure 1. FT-IR diffuse reflectance spectra (6200-5300 cm-1) of Zantac 75 (R) (top trace), and two generic ranitidine formulations (middle and bottom trace).

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FT-NIR Tablet analysis using MPA

OPUS/LAB is a user friendly software package

MPA spectrometer with complete accessory

FT-NIR

An Example

Zantac 75® is a non-prescription, brand-name pharmaceutical, used for treatment of excess stomach acid. The active ingredient is ranitidine hydrochloride, which is also available in generic formulations. The differences between the formulations make it possible to distinguish the brand-name drug from the generic counterparts using near-infrared spectroscopy.

Experimental

Samples of Zantac 75® and two generic ranitidine formulations were tested. Spectra were obtained using a Bruker MPA equipped with an integrating sphere for sampling in diffuse reflectance. Since diffuse reflectance is a surface-sensitive technique, and because some of the samples had printing on one side of the tablet, spectra were obtained of both sides of all of the tablets tested. Spectra were taken at 8 cm^{-1} resolution, 32 scans per spectrum.

Spectra of the three samples are shown in Figure 1. Substantial differences can be observed between the Zantac (upper trace) and the two generic formulations (middle and bottom traces). These can be used with a conformity test to provide a yes/no identification of the suspect product.

Automation and User Interface

The user interface to the spectroscopic system can be simplified with the use of OpusLab, providing a system usable by non-technical personnel that provides unambiguous results.

Conclusion

Verification of the identity of a pharmaceutical product has been demonstrated using a Bruker Optics FT-NIR spectrometer. The speed and precision of this analytical system can aid health authorities in their fight to protect the public from the increasing trade in counterfeit pharmaceuticals.

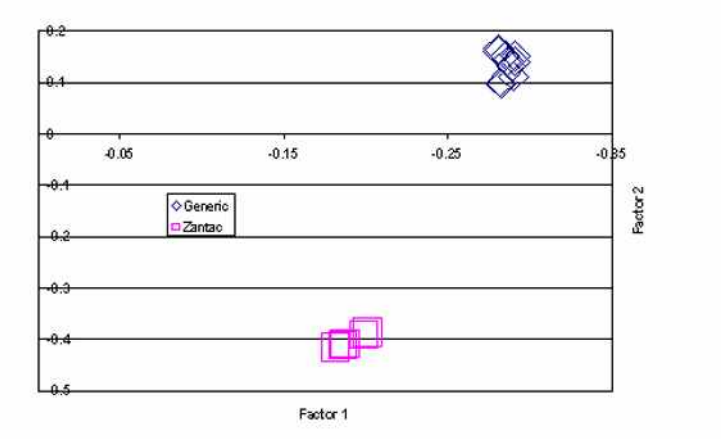

Figure 2. Factor analysis graph demonstrating the ability of the Opus software to distinguish between the name-brand pharmaceutical and the generic product.

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