

# Identification of Counterfeit Pharmaceuticals Using the RamanStation 400

## Introduction

In recent years there has been significant growth in the counterfeiting of clothing, computer games, music and alcohol. Since the early days of counterfeiting, organized crime has become heavily involved and the practice now extends to pharmaceuticals.

There are three main types of counterfeit pharmaceuticals:

- Incorrect API or polymorph
- Correct API but incorrect excipients
- Re-packaged, out-of-date but genuine pharmaceuticals

The result of pharmaceutical counterfeiting might be as subtle as the drug's failure to cure a headache. However, if a counterfeit material is used to treat serious illness such as malaria or HIV/AIDS, the result could be fatal.

In the developed world, counterfeiting is mainly restricted to easily recognized products such as Viagra™ or Tylenol™. In the developing world however the practice of counterfeiting is widespread. The World Health Organization estimated the sales of counterfeit drugs to be worth up to \$40 billion in 2006.<sup>1</sup>

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## Raman analysis of tablets and packaging

Raman spectroscopy is particularly suited to the analysis of counterfeit materials as it is non-destructive and can be used to assess both the authenticity of the packaging as well as the pharmaceutical product.

It is often the case that the packaging is printed to look authentic but the inks used are seldom the same as on the genuine product. Raman analysis of ink used in the packaging can be a simple discriminator when identifying counterfeit products. In Figure 1 the differences can clearly be seen between the red ink from the authentic packaging and the ink from an identical-looking counterfeit package. This technique is particularly useful if analyzing repackaged, out-of-date product. Analysis of the polymers in blister packs can also be used to identify repackaged product.

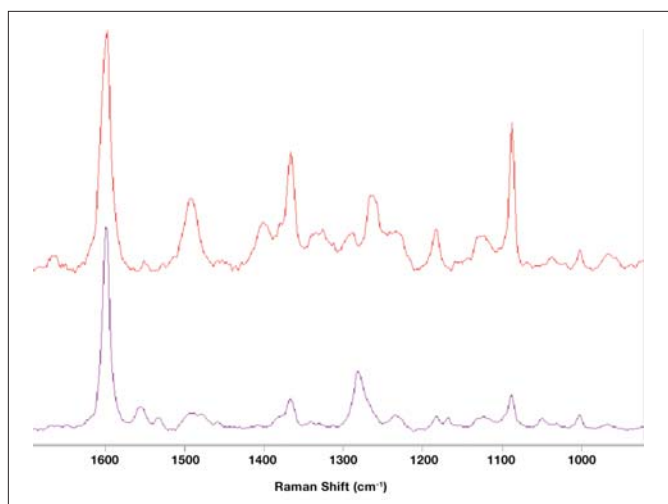


Figure 1. Comparison of Raman spectra of ink on outer cardboard packaging of authentic (upper spectrum) and counterfeit (lower spectrum) pharmaceuticals, analyzed on RamanStation 400.

However, analysis of the tablets themselves is the most discriminatory. In order to maximize profit, forgers will either forego the use of API in the product or use a cheap API such as aspirin or acetaminophen. More expert forgers might use the correct API, but have the incorrect blend of fillers (e.g. lactose) and lubricating agents (e.g. magnesium stearate).

As can be seen in Figure 2, the genuine pharmaceutical tablet gives a spectrum of a complex blend of API and excipients while the counterfeit material shows a Raman spectrum consisting entirely of lactose and cellulose.

## References

1. Katie Merx, "Can you tell which pills are fake?", Detroit Free Press, July 26, 2006, and Judy Alta, "Counterfeit Drugs Seen as Growing Problem," The United States Mission to the European Union, November 16, 2006.

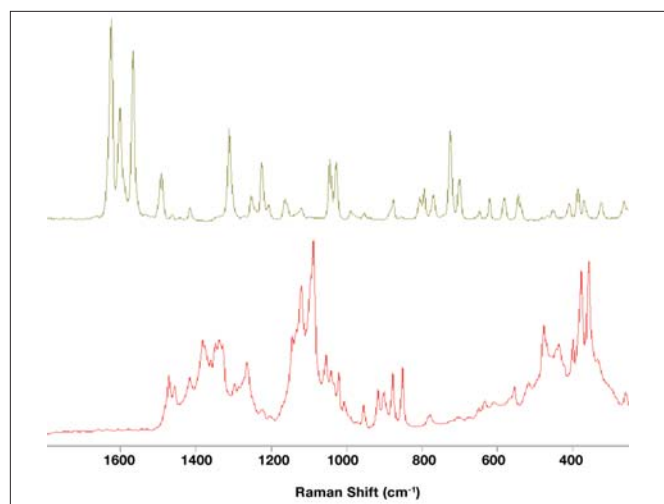


Figure 2. Raman spectra of authentic (upper spectrum) and counterfeit (lower spectrum) tablets, analyzed on RamanStation 400.