

Handheld Confidence.

APPLICATION NOTE

ON-SITE DETECTION OF COUNTERFEIT MEDICINES & HEALTHCARE PRODUCTS WITH HANDHELD RAMAN

- RESULTS IN THE FIELD
- MEASURE A WIDE RANGE OF MATERIAL TYPES
- DETERMINE AUTHENTICITY IN SECONDS

Counterfeit pharmaceuticals and other health care products are a global problem and include not only products containing potentially harmful substances, but also products that contain no or diluted amounts of active pharmaceutical ingredients (API). Because of this growing problem, the need for fast and easy screening techniques in the field has become increasingly urgent.



QUICK COUNTERFEIT IDENTIFICATION WHILE MINIMIZING FLUORESCENCE

Identification of Pharmaceuticals

Raman spectroscopy is highly specific to chemical composition and so is well suited for distinguishing authentic vs. counterfeit products. A common challenge of traditional handheld Raman instruments using 785nm excitation is fluorescence interference. The higher excitation wavelength of the handheld Rigaku Progeny 1064nm analyzer minimizes this signal blocking fluorescence. To demonstrate this advantage, a green gel cap of an over the counter (OTC) headache relief medication was measured with a handheld Raman analyzer using 785nm and Progeny, using 1064nm excitation. As seen in Figure 1, the 785nm excitation shows a broad curve which is from fluorescence and obscures any material specific Raman peaks. However, the 1064nm excitation of Progeny clearly shows specific Raman peaks that can be used to identify an authentic material.

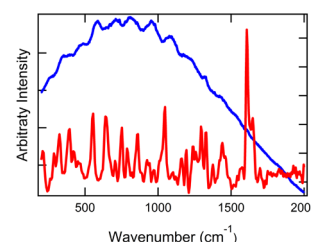


Figure 1. 1064 nm excitation and 785 nm excitation Raman spectra from a green capsule of over the counter headache relief medication.

Authentication of Pharmaceuticals

The next figures show two examples of how different the Raman spectra can be for authentic vs. counterfeit pharmaceuticals. Figures 2 and 3 respectively show Raman spectra of authentic and counterfeit Cialis tablets and authentic and counterfeit commercial pain relief powders. All of these spectra were collected with a 1064nm handheld Progeny analyzer using measurement times of less than 30 seconds. In both cases, Progeny can easily distinguish the counterfeit from the authentic, as the Raman spectra are clearly different from each other.

The authentic commercial pain relief medication is a mixture of three APIs: acetaminophen (paracetamol), aspirin and caffeine. When the Raman peaks of the authentic and counterfeit are carefully compared to each other, and then compared to the spectrum of pure caffeine, it appears that at least the amount of caffeine in the counterfeit powder is much less than in the authentic. It is also therefore likely the ratio of the acetaminophen and aspirin is different as well. A lack of caffeine in the counterfeit can reduce the efficacy of the medication. For an OTC pain relief medication reduced efficacy may be of most concern for the manufacturer, but for many other types of life saving medication a counterfeit without the correct API can have disastrous consequences.

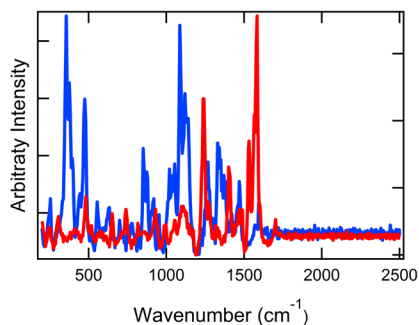


Figure 2. 1064nm Raman spectrum of authentic and **counterfeit** Cialis tablet cores.

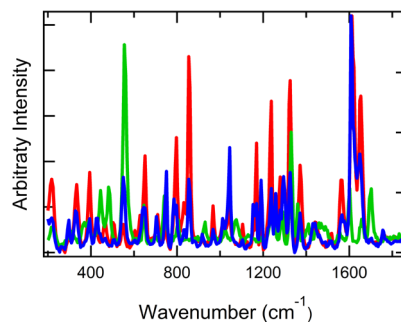


Figure 3. 1064 nm Raman spectra of authentic, and **counterfeit** commercial pain relief powders and pure **caffeine**.

Health Care Products

Counterfeit health care products may not have the same potential for disastrous effects as counterfeit pharmaceuticals but in terms of profit and possible reputation loss counterfeit products are still a major problem for their manufacturers. Figure 4 shows 1064nm Progeny Raman spectra of an authentic and counterfeit brand name toothpaste. Again the authentic and counterfeit Raman spectra are clearly different. Interestingly the Raman spectrum of the counterfeit brand name toothpaste matches very closely with calcium carbonate, which is a common toothpaste ingredient, but one that is not present in this brand name toothpaste.

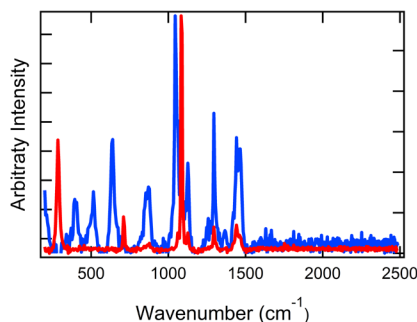


Figure 4. 1064nm Raman spectra of **authentic** and **counterfeit** brand name toothpaste.

CONCLUSION

Handheld Raman spectroscopy provides regulatory enforcement agencies and manufacturers the ability to examine the chemical composition of commercial products on the spot, resulting in rapid identification of counterfeits and immediate removal from the supply chain. These analyses demonstrate the ability of Raman to distinguish authentic and counterfeit pharmaceutical and health care products quickly and easily with a robust field portable instrument. They also show the advantage of using a 1064nm excitation handheld Raman vs. a 785nm handheld Raman in order to reduce fluorescence and achieve better identification of some products. The combination of 1064nm excitation, Raman's specificity to distinguish authentic and counterfeit products, and the ease, portability and high spectral quality of Progeny make it an ideal analysis tool for determining authenticity in the field.