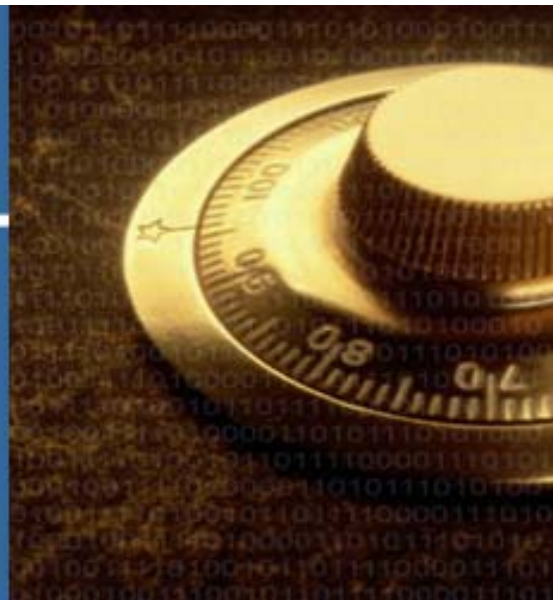


PHAZIR Rx™

Detecting Counterfeit Pharmaceuticals using Handheld Near-infrared Spectroscopy



*S. Assi, R. Watt and A. Moffat,
The School of Pharmacy, University of
London*

Pharmaceutical counterfeiting is a critical issue accounting for 10 % of the world market by revenue. The impact of pharmaceutical counterfeiting can be counted in monetary loss, delayed healing, and increased morbidity and mortality. The World Health Organization and national regulatory agencies worldwide attempt to identify and prevent the sale of potentially lethal counterfeits. The problem is complex because of the vast number of pharmaceutical formulations, global manufacturing and buying patterns and the wide variety of counterfeiting techniques.

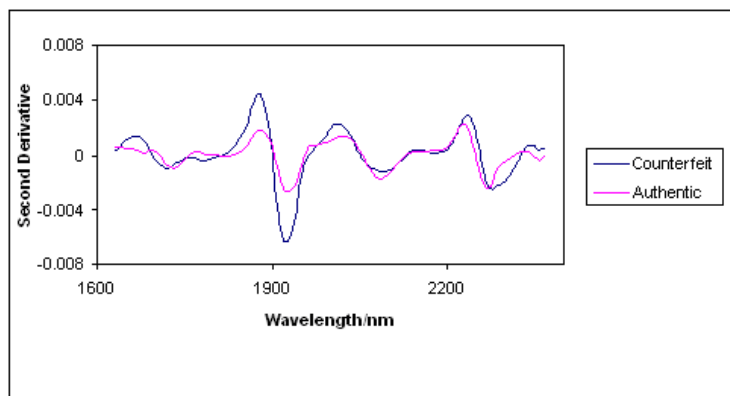


Figure 1. The second derivative NIR spectra of authentic and counterfeit Plavix Tablet 75 mg. The PHAZIR™ NIR system can easily distinguish between these products as the spectra have a correlation coefficient of only 0.86.

There are a number of strategies poised to answer the challenge of screening for counterfeits. Authentication using color-changing inks, universal serialization, barcodes and radio-frequency identification tags can verify the supply chain while analytical methods including chromatography, isotopic characterization and optical spectroscopy can confirm the composition

Near-infrared (NIR) spectroscopy has a direct implementation and is highly specific. The NIR spectrum of each pharmaceutical product is specific to its formulation. Even the physical properties of formulations, such as tablets, have signatures from the manufacturing process, including particle size and hardness. Counterfeits, although appearing identical to the eye, can be readily distinguished by their NIR spectra (Figure 1).

Handheld NIR instrumentation makes the process of inspection rapid, efficient, and surprisingly, inexpensive. NIR spectrometers can directly analyze a pharmaceutical product without preparation and results can be obtained within five seconds or less. The portability of a handheld instrument allows for efficiency in the screening process.

Handheld instruments are ideal for rapid screening. The portability of a hand-held instrument can allow inspectors to investigate the contents of a mixed shipment easily. Rapid analysis of individual suspect containers can be immediately compared to a reference library of spectra from batches of the pharmaceutical product. Results are immediate and authentic shipments can be allowed through. Suspect materials can be segregated and subjected to a more thorough analysis of the contents and documentation to determine the material's authenticity and origin.