

Handheld Analyzers for the Rapid and Accurate Screening of Counterfeit Pharmaceuticals

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Counterfeit and substandard medicines have serious human health and economic costs

The magnitude of the counterfeit and substandard drug problem has gained significant public attention due to a number of high profile incidents and greater media focus. According to the Centers for Disease Control and Prevention (CDC), an estimated 10%–30% of medicines sold in developing countries are counterfeit. In the industrialized world studies show on-line pharmacies have opened a significant portal for counterfeit medicines to unsuspecting consumers. The World Health Organization (WHO) asserts that counterfeiters have likely succeeded in producing an illegal industry with annual sales exceeding \$75B. Most significantly, hundreds of thousands of lives will be lost each year due to the menace of counterfeit medicines (International Policy Network).

In some cases, product degradation may occur in the absence of any malfeasance, sometimes with equally serious consequences. Lack of confidence in the quality of medicines has far-reaching negative implications for both patients and pharmaceutical companies. Whether due to poorly controlled supply chains and quality control procedures or outright criminal intent, counterfeit and substandard medicines represent a serious problem.

Traditional approaches to combating counterfeits are inadequate

For many years, pharmaceutical companies have relied on a combination of covert and overt security features in packaging and occasional forensic analysis to identify counterfeit drugs. However, counterfeiters have found ways to quickly and accurately replicate those features to deceive authorities and patients. Traditionally, the only real way to reliably determine the authenticity of a suspect product has been through laboratory analysis by trained chemists. But, this approach has limited throughput and until recently could only be used for a small fraction of all suspected samples and not for routine screening.

Portable analyzers bring pharmaceutical authentication from the laboratory to the field

In an age where smartphones and computers are becoming both smaller and more powerful, it may

come as no surprise that the same trend is starting to catch on with sophisticated instruments formerly found in analytical chemistry laboratories.

Instruments such as Thermo Scientific portable analyzers are designed for ease of use so that users without advanced degrees can perform analysis for a wide range of applications.

The Thermo Scientific TruScan GP and TruScan RM analyzers, powered by Raman spectroscopy, and microPHAZIR RX analyzer, powered by NIR spectroscopy, offer two complementary approaches to authenticating pharmaceuticals. These analyzers use vibrational spectroscopy to compare the chemical “fingerprint” of a sample with an authentic reference. Spectroscopy is the characterization of a substance based on the way it interacts with



The TruScan GP analyzer can be used in the field to provide rapid identification of counterfeit pharmaceuticals.

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light. The bonds between molecules react to photons of light to create very unique, distinct spectra characteristic of the type and number of bonds in the sample. Different types of bonds show up as peaks of varying intensity in the resulting spectrum, creating a unique “fingerprint” for a particular compound. These techniques have recently become available in a portable form factor in which the analysis is automated to provide meaningful answers to the user. Because the spectrum generated by the spectrometer represents all the components of a pharmaceutical dosage form, including the active ingredients, excipients, fillers, dyes, and coating materials (and their relative concentrations), any deviation from the original formulation will lead to a detectable change in the resulting spectrum. This makes it virtually impossible for counterfeiters to fool the instrument. Substandard products with the right ingredients, but inadequate amounts of active ingredient, can also be identified by their spectra.



The TruScan GP and TruScan RM analyzers, powered by Raman spectroscopy, and the microPHAZIR RX analyzer, powered by NIR spectroscopy, provide field-ready solutions in support of the war on pharmaceutical counterfeiters

The operation of these analyzers is simple. The instruments contain a database of pharmaceuticals created by the user. These authentic references are called methods and are easily created by scanning a known authentic substance with the instrument and saving the resulting spectrum to the instrument’s memory. Methods can be copied from one instrument to any number of additional instruments electronically such that fleets of instruments can be broadly deployed. When field users test a sample – whether it is a suspect sample or a random inspection – the instrument provides a simple “pass” or “fail” result based on sophisticated

chemometrics comparing the spectrum of the sample with the reference spectrum. For samples that fail, the instrument can search its library to determine whether it matches another known substance or mixture of substances. All results are securely stored on the instruments until downloaded.

National Regulatory Agencies Currently Using Thermo Scientific Portable Analyzers

- Canada – Health Canada
- China – CFDA
- Denmark – DMA
- France – ANSM
- Indonesia – NAFDC
- Netherlands – Dutch Medicines Authority
- Nigeria – NAFDAC
- Sierra Leone – Ministry of Health
- Switzerland – SwissMedic
- Thailand – FDA
- Uganda – National Medical Stores & NDA
- United Kingdom – MHRA
- United States – US FDA

New technology provides a new approach to anti-counterfeiting

This remarkable innovation is allowing brand owners and government agencies to develop new and powerful approaches to their anti-counterfeiting strategies. The majority of the top twenty pharmaceutical manufacturers use the TruScan and microPHAZIR analyzers to verify the identity of either raw materials or finished products. Regulatory agencies in North America, Europe, Asia, and Africa have purchased the analyzers to bolster their anti-counterfeiting efforts. In some countries, regulatory authorities have successfully deployed significant numbers of the instruments to conduct random field screening from the ports of entry to the point of sale. These have facilitated the seizure of thousands of counterfeit drugs that would otherwise have entered the supply chain with serious consequences.



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