

SPECTRAL EVOLUTION

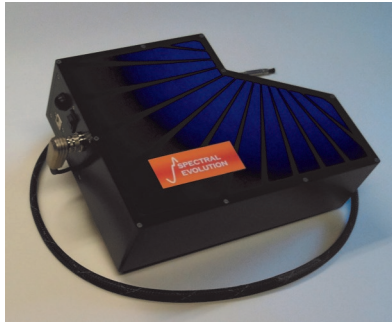
Using an NIR Spectrometer to Identify Counterfeit Drugs

According to INTERPOL, worldwide drug counterfeiting is now a multi-billion dollar industry. While the large majority of counterfeit drugs are sold into developing nations (e.g. counterfeit malaria drugs in Africa) even the United States has seen a rise in counterfeits, thanks to the availability of these drugs over the Internet.

Counterfeit drugs are detrimental in three primary ways:

- ◆ Patients don't receive the correct drug—leading to potential injury and/or death
- ◆ Patients receive contaminated versions of the correct drug, which may be toxic
- ◆ Pharmaceutical companies lose billions of dollars in revenue

Visual inspection, especially of drug packaging, and traceability through package identification such as bar codes, are the most common methods for identifying counterfeits. However, counterfeit packaging is often very close to the original, even down to the identification codes. With an NIR spectrometer, such as the SM-3500 spectrometer from SPECTRAL EVOLUTION, it is possible to identify the authenticity of a drug directly through its packaging, including bottles and blisterpacks, and through capsule shells for drugs with encapsulated ingredients.



SM-3500

An NIR spectrometer can help combat counterfeiting by allowing identification and authentication using spectral matching and principal component analysis. Principal steps involved in these measurements include:

- ◆ Taking sample spectra of authentic drugs to form a known reference
- ◆ Check the target drugs against those spectra for specific confirmation

The portability of the SM-3500 spectrometer makes it well-suited to this type of application, since it can be performed in the field at:

- ◆ Manufacturing facilities
- ◆ Warehouses
- ◆ Hospitals
- ◆ Pharmacies
- ◆ Field operations for government agencies

With third party software such as GRAMS from Thermo Scientific, the SM-3500 can also be used for quantitative analysis of a drug's chemical composition.

Counterfeit Drug Applications

- ◆ Minimal or no sample prep
- ◆ Rapid analysis—as quickly as 1 second per tablet
- ◆ Non-destructive—perform analysis with the drug still in its packaging
- ◆ Information on structural and chemical characteristics
- ◆ Spectral match to authenticate drugs
- ◆ Portability for field use in manufacturing, warehouse, hospital, clinic, pharmacy, any facility
- ◆ Screening for anti-malarial drugs in developing nations in Africa and Asia
- ◆ Identification of criminal and substandard counterfeits
- ◆ Apply to a wide range of drug types, including antibiotics, anti-protozoals, hormones, steroids, anti-asthma, anti-allergy, anti-malarial, analgesics, and many more
- ◆ Chemometric analysis of samples provides more in-depth information including API (active ingredients) concentrations
- ◆ Also able to analyze excipients (non-active ingredients) for authentication
- ◆ Useable with physical-chemical identifiers/markers in genuine drugs
- ◆ Potential use as a field screening tool by non-scientific personnel

GRAMS is a product of Thermo Scientific. SPECTRAL EVOLUTION is an authorized reseller of GRAMS.

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