

InfraTrac[®] and the Polychromix PHAZIR[™]

Combating Counterfeit Pharmaceuticals: A Tag and Track Solution



Companies need reliable ways to ensure the integrity of the pharmaceutical supply chain. Patients are in danger from counterfeiting and diversion, errors, and impure or counterfeit ingredients.

Until recently, the approach to product protection was expense: the more expensive the tag, the reasoning went, the less likely the counterfeiter was to be able to copy it. For practical reasons, most of the protection ended up on the package, in the vain hope that the product and the package would always stay together.

InfraTrac's novel approach to anti-counterfeiting protects the product, not the package, but without trying to out-spend the counterfeiter. Other substance-based approaches use complex new technologies, such as nanoparticles or DNA fingerprints. These can be expensive to implement, and expensive to alter.

InfraTrac's approach, sophisticated yet lightweight and flexible, uses the existing ingredients in a formulation, and turns those into a fingerprint. The near-infrared (NIR) spectrum of each pharmaceutical product is specific to its formulation. With a handheld instrument, it is fast and easy to analyze the product. Using InfraTrac's formulation fingerprint, each production line, or even each lot, can be tagged – but without using any external substances.

The U.S. Food and Drug Administration allows for post-approval changes in inactive ingredients: up to 5% of excipients may be altered under the FDA SUPAC-1 guidelines, with just an annual notification letter. The European Union permits 10% changes. That margin is easily detectable with NIR.

With a handheld instrument, suspect materials can be screened rapidly, and compared to a reference library of spectra from batches of the pharmaceutical product. Results are immediate, and authentic, non-diverted shipments can be allowed through. Suspect materials can be subjected to additional analysis of the contents and documentation to determine the material's authenticity and origin.

InfraTrac's formulation approach puts a lot number, so to speak, into the product itself, without a unit cost. Formulation fingerprinting cannot be reverse engineered, so even a counterfeiter who can read NIR spectra cannot determine the formulation itself, quantitatively or qualitatively. Detection with NIR takes only seconds. The test is non-destructive, so it can be repeated in front of a jury.

Tag and track the substance itself: Lightweight, safe, and flexible.