Modern medicine allows us to treat more illnesses than ever before, reducing human suffering and extending lifespans beyond what was possible even in the recent past. In order to fully harness the potential of pharmacological development and adhere to industry regulations, pharmaceutical manufacturing employs strict assessment protocols, ensuring optimal quality control and consumer safety. Spectral analysis using Near-Infrared (NIR) spectroscopic imaging is a widely used, effective, and easily integrated method of analysis that quickly provides valuable information regarding the composition of pharmaceuticals. By integrating NIR spectrophotometers in pharmaceutical production lines, manufacturers can obtain detailed measurements of a variety of drug features to guarantee efficacy and identify contaminants that compromise the potency and safety of the product in question.

Ensuring Safety and Efficacy

Pharmaceuticals are powerful products that require precisely formulated compositions to offer <u>full</u>, <u>predictable benefit to the consumer</u> while preventing harmful effects; due to the nature of the product, pharmaceutical manufacturers have a heightened responsibility to ensure product safety and effectiveness. When consumers purchase a drug, they are relying on the manufacturer to guarantee a particular dosage that will allow them to use the product in a beneficial way. By analyzing the absorption spectra, the manufacturer can both confirm the presence of the active ingredients and identify the concentration of the ingredients to ensure proper dosage. NIR spectroscopic imaging gives operators instant information about the quality of the blend and alerts them to improperly mixed product that can interfere with efficacy and pose health hazards.<u>1</u> In doing so, the manufacturer can be assured that they are releasing only correctly formulated products into the marketplace that will provide therapeutic benefit to consumers.

Identifying Contaminants

Spectral analysis also alerts operators to the presence of contaminants and allows them to potentially identify unknown impurities. Certain organic compounds produce distinctive spectra that act as a fingerprints, taking the guesswork out of contaminant classification. The ability to quickly identify impurities allows manufacturers to determine whether or not the integrity of the product has been compromised, evaluate safety risk, and chart a course of action to both handle contaminated product and modulate the production process to prevent future interference.2

Toward In-Process Analysis

Traditionally, the pharmaceutical industry has concentrated on end-product analysis, testing finished products that have gone through the completed manufacturing cycle. However, today's changing economic environment has caused re-evaluation of traditional analytical methods in an effort to increase manufacturing efficiency and seek out cost-savings. As such, in-process analysis is increasingly becoming seen as the way forward in pharmaceutical production. By integrating spectrophotometers in the production line, operators are instantly notified of process changes, can take early corrective action, and are able to contain defective product before it is released into the marketplace. Rather than incurring the expense of scrapping product at the end of the production line, continuous in-process monitoring of product quality allows operators to immediately identify problems when they happen and intervene to restore equilibrium.

Full article with photos available here:

https://www.hunterlab.com/blog/color-pharmaceuticals/applications-of-spectral-analysis-measuring-the-peaks-and-valleys-of-pharmaceutical-quality/