

Measuring the color and shape of drugs during the manufacturing process can catch mistakes before the final product appears.

Image Source: Flickr user .v1ctor Casale.

In a competitive marketplace, companies go with the most economically viable processes that get their products on the market to start bringing in revenue. Unfortunately for consumers and public health, maintaining high levels of production without proper quality control has historically been very affordable for the pharmaceutical industry—an economic reality which has tainted public opinion of the industry over time, as consumers have faced drug recalls and the subsequent shortages.

For pharmaceutical companies, it could seem like a Catch-22 to offer an unaffordable product with consistent quality and be edged out of the market by low-cost competitors, or keep production rates high and write off the costs of drug recalls and subsequent shortages as a necessary expense. Fortunately for manufacturers and consumers, a portable, affordable quality check tool—the spectrophotometer—can analyze the formulation and consistency of a pharmaceutical with a preternatural degree of accuracy, making it ideal for small molecule pharmaceutical manufacturers.

The Regulatory Utopia: Full Compliance with Less Oversight

Federal oversight measures, such as regulatory fines from the FDA, have worked toward quality products, measuring quality by criteria including sanitation, properly maintained equipment, properly trained personnel, and effectively responding to consumer complaints. However, according to the Brookings Institute, "quality issues remain a frequent occurrence."¹ The FDA envisions changing that by incentivizing compliance to help companies develop a corporate culture that actually values accountability, rather than viewing it something they have to meet to avoid fines.

As the FDA pushes for pharmaceutical companies to achieve a quality-driven corporate culture and reduce recalls and related drug shortages, manufacturers can take steps in good faith toward delivering the medicines we need safely and consistently by investing in advanced quality control instruments like the spectrophotometer. It's time for companies to make a good show of faith with both the public and with regulatory groups such as the FDA and guide the industry in the right direction: where we are all working as a society toward a healthier public.



Spectrophotometers can play a key role in the R&D phase of pharmaceutical development, allowing companies to detect potential problems well before spending large amounts of money on research. Image Source: Flickr user jpalinsad360

Analyzing Color: the Affordable Quality Control Solution

A spectrophotometer analyzes the chemical makeup of pharmaceuticals by measuring the light reflected by the material at a molecular level. You could say that a spectrophotometer analyzes "color"—but not in the sense that our eyes do, which is highly subjective and <u>prone to</u> <u>miscalculation</u>. By accurately measuring the wavelength of the light reflected in a material, the spectrophotometer can determine exactly the substances that comprise a sample, making it ideal for pharmaceutical applications.

Integrating the Spectrophotometer into the Lab

To manifest the ideal regulatory environment that the FDA envisions, where pharmaceutical companies have cultivated a corporate culture of high standards and regulatory compliance, the tools used in quality control must be affordable and easy to use. The companies that can meet that expectation are going to excel in the market by proving their reliability and accountability, but first they need the tools to integrate regular quality control checks at different points in the production process—at a price that's going to be viable in a competitive market.

Fortunately, the portability of the spectrophotometer makes it easy for technicians to spot-check at different points in production without excessively disturbing production. Handheld units allow technicians to analyze and spot-check lab samples with absolutely minimal disturbance or expense to the usual workflow.



Spectrophotometers allow for easy evaluation of small molecule drugs in different forms, including powders, creams, and liquids.

Image source: Flickr user whiskeyandtears

Spectrophotometers for Pharmaceutical Application: What's on the Market

HunterLab offers affordable, portable spectrophotometers for pharmaceutical application, that can be used to measure color as a quality control measure in liquids, creams, powders, or solids. Quality and reliability don't have to be expensive; in fact, the results you see from integrating spectrophotometers for regular quality checks are a market differentiator for your company as you pave the way toward changing corporate culture in the pharmaceutical industry. Let's keep our society healthy.

To begin integrating HunterLab spectrophotometers into your pharmaceutical production process, please <u>contact us</u> today for more information.

 "Measuring Pharmaceutical Quality through Manufacturing Metrics and Risk-Based Assessment," May 2014, http://www.brookings.edu/~/media/research/files/papers/2014/05/01-quality-metrics-

fda/quality-metrics-meeting-summary.pdf