

Many pharmaceutical companies choose to test small sample sizes when the cost of the product is especially high. Image Source: Shutterstock user Iryna Imago

In an ideal world, drug manufacturers could test large batches of any material for color consistency and quality. However, this isn't a reality for many pharmaceutical companies. Often, the active ingredients that go into a life-saving cancer treatment or a promising new Alzheimer's medication are expensive to develop, difficult to synthesize, or made from rare, finite natural resources. This means that drug manufacturers have to carefully measure out their test samples, and in some cases, the material is so expensive that they need to be particularly frugal with their sample sizes. For instance, Soliris, a drug used to treat a very rare genetic condition called atypical hemolytic-uremic syndrome, is one of the most expensive medications in the United States—it sells for \$18,000 per dose.<sup>1</sup> In order to perform quality control tests on an expensive medication like this, manufacturers typically opt for the smallest sample sizes possible to avoid wasting product.

But when your sample size decreases, it can make the color measurement process much more complicated, as many color measurement instruments are incapable of accurately analyzing the color of very small samples; the equipment is typically designed with larger sample sizes in mind, and these one-size-fits-all tools lack the accessories required to measure micro samples. However, there are a number of <u>high-quality spectrophotometric instruments</u> and accessories on the market that are designed specifically to measure small samples with the highest degree of accuracy. When you use one of these instruments in your lab, you can significantly shrink your sample size requirements, helping you preserve valuable materials.

## Why Color Consistency Matters

Measuring the color of your pharmaceutical products is important for two primary reasons. First, the color of a drug can help you determine whether there are <u>impurities or contaminants</u> in your sample; if a liquid cough suppressant is supposed to be completely clear, yet your

spectrophotometer detects a yellow tint, then it's possible that your sample was contaminated, or that there is something wrong within your manufacturing line. The second reason color measurement is important is <u>customer perception</u>. Generally, customers are more likely to trust medications that are consistent in color from pill to pill or batch to batch. Additionally, studies have shown that the color of a medication can impact users' perception of sensory experience and efficacy. The color of medication can even affect whether users adhere to their prescribed medication plans, making color critical to ensuring therapeutic benefit.<sup>2</sup> However, when you're working with scarce or costly medications, the color quality control process can also grow expensive or even compromise medication supply. You have to waste a certain amount of product in order to test for color consistency, and the more expensive your product is, the greater impact your test sample size has on your bottom line and the availability of usable medication.



Testing small liquid samples requires the use of specialized color measurement accessories. Image Source: Shutterstock user Davizro Photography

High Manufacturing Costs Require Smaller Test Samples

There are a number of reasons medications are expensive to produce. Some of the most notoriously expensive pharmaceutical products, for example, are biologics. This category of medicine includes vaccines, antibodies, and recombinant proteins (made when a lab joins genetic material from different sources). It's the fastest-growing category of products in the pharmaceutical industry; in 2008, biologics made up almost 30 percent of the 100 top-selling drugs in the world and that number is increasing. Biologics are manufactured using a biological process, not a chemical process. Because these products are made from raw materials that are rare and difficult to produce, the price of these products is typically much higher than it is for drugs made using synthetic chemical processe; just one dose can cost as much as \$10,000.<sup>3</sup>

If you manufacture your products using any rare raw materials, the scarcity and extra cost associated with these ingredients may force you to use smaller sample sizes when testing for color consistency. For instance, some chemotherapy drugs contain platinum, which is among the most expensive metals in the world.<sup>4</sup> Another chemotherapy drug called Taxol is made from the bark of an extremely rare tree, the Pacific yew. These trees only exist in old-growth forests in the Northwestern United States, and it takes at least 60 pounds of bark to produce enough of the drug to treat just one patient.<sup>5</sup> Because this resource is finite, manufacturers must handle their test samples with care. Regardless of the reason for high cost or scarcity of material, many pharmaceutical manufacturers can benefit from small sample testing; the less product you waste during testing, the more product you can put into the hands of those who need these invaluable medications.



Small sample accessories can help you test expensive materials without wasting more product than necessary. Image Source: Shutterstock user Syda Productions

## How to Measure Small Sample Sizes

To test an especially small sample size, you'll need a repeatable measurement method designed accurately analyze your sample size. Many of HunterLab's spectrophotometers are compatible with <u>specialized accessories</u> that allow you to accurately test small and micro sample sizes consistently. The accessory that you will find most beneficial depends on the type of product you're manufacturing, what the minimum size of your sample will be and the type of spectrophotometer that you already have in your lab. These may include:

## Measuring Powder Samples in Reflectance Mode

If you're working with powders, you'll need to modify your spectrophotometer's port plate in order to get accurate color measurements from a very small sample size. HunterLab instruments that include a Small Area View (SAV) option can be equipped with a smaller port plate as an accessory. In addition to the smaller port plate, you can use a special powder holder that measures about 0.4 ccs

of <u>pressed powder</u>. To use this method, simply place your powder sample into the holder, pack it down with the plunger that comes with the accessory, and then place it inside of the port plate, where it will be measured via the clear window on the holder.

# Measuring Solid Samples in Reflectance Mode

If you're working with any small solid samples, then you'll need to reduce the size of the port opening on the spectrophotometer. This will allow you to view the sample without a background. Many of HunterLab's spectrophotometers are able to switch from a Large Area View to a Small Area View automatically, using a motorized component. To use a SAV on your small solid sample, you should operate the instrument via the retroviewer option so that you can ensure that the entire solid sample covers the port opening. Be aware, however, that your sample size needs to be at least as large as the openings (4 mm or 3 mm, depending on the instrument).

# Measuring Liquid Samples in Transmittance Mode

If you're working with liquids, you'll need a specialized semi-micro cell holder for your samples. HunterLab has a semi-micro cell holder accessory available that includes beam-reducing optics to take accurate measurements of small liquid samples. This accessory needs to be installed in the transmission compartment of the instrument. A typical 10mm pathlength cell requires 3500µL of solution, HunterLab offers mirco and ultramicro cells that can be measured with a little as 300µL of solution.

# HunterLab Innovation

With specialized accessories like smaller port plates, semi-micro cell holders, and powder holders, HunterLab provides reliable solutions for even the most exacting color measurement challenges. Our instruments are designed to meet the high standards set by the <u>pharmaceutical industry</u>, and over the past 60 years, we have been a leader in dependable color measurement of liquid, solid, and powdered medications. <u>Contact us</u> today to learn more about our spectrophotometers, customizable software packages, and world-class customer support services and let us help you select the right tools for your needs.

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