If you've ever purchased your favorite brand of over-the-counter medication while you're on vacation, you know that brand-name pills, powders, and liquids often look exactly the same no matter where you are in the world. Even when you travel thousands of miles away, your preferred brand of allergy tablets will likely be the same reliable shade of bright orange, whether you're buying the tablets in London or New York. In order to supply medications to these many different cities, large-scale pharmaceutical companies typically operate hundreds of manufacturing facilities around the world.

But with so many different manufacturing facilities, how do pharmaceutical companies maintain precise color consistency in their products? They accomplish this by standardizing their manufacturing and testing process. More specifically, large-scale companies use methods like <u>Hitch Standardization</u> to ensure that all of their manufacturing facilities perform color quality control tests in precisely the same way. By standardizing the color quality control process across different manufacturing locations using Hitch Standardization, you can produce medications that are perfectly consistent in color.

How Color Consistency Benefits the Pharmaceutical Industry and Consumers

Color quality control is a vital aspect of the pharmaceutical industry. Not only can consistent color be <u>a sign of</u> <u>proper formulation and a significant safety mechanism</u>, it also deeply impacts <u>consumer perception of</u> <u>medication</u>. Additionally, manufacturers of brand name medications rely on color consistency to help them gain a greater share of the market and establish their brand identity in the eyes of their customers. For these manufacturers, the product's unique trade dress (the appearance of the product) could significantly increase a customer's loyalty and trust in the brand.<u>1</u>

And color consistency isn't just important for <u>over-the-counter medication</u> manufacturers; pharmaceutical companies that produce prescription drugs also have to ensure that their products are consistent in color, in part due to the effect color has on both patient behavior, <u>including adherence</u>. For example, studies have shown that people are more likely to take their prescribed medications as prescribed when they see that their pills are the same color every time they refill their prescriptions at the pharmacy.<u>2</u> If the pill color suddenly changes, then people are less likely to take them as prescribed. As such, color consistency isn't merely a marketing tool—it can have a very real impact on patient health and wellbeing.

Large-Scale Manufacturers Often Struggle with Color

Consistency

Although color consistency is critical in the pharmaceutical industry, it can be very difficult to achieve, especially for large-scale companies. Many large pharmaceutical companies manage hundreds of different test labs and manufacturing facilities around the world. For example, Johnson & Johnson oversees a network of 120 separate manufacturing facilities in more than 60 different countries.<u>3</u> With so many manufacturing and testing facilities operating simultaneously, it can be challenging to identify and enforce consistent sample measurement standards. This is why many pharmaceutical companies use Hitch Standardization to ensure that every product they create is being measured in exactly the same way.

What is Hitch Standardization?

Hitch Standardization is a process in which two different spectrophotometers are made to read the same color values for a sample by "hitching" one reference spectrophotometer to a secondary spectrophotometer. The secondary unit is mathematically calibrated so that it reads the same color value as the reference unit. This is done by manually inputting the color values from the reference unit into the secondary unit's processor.

The theory behind Hitch Standardization is that as long as the spectrophotometers are similar in design and have the same geometry, then these instruments can be calibrated to display almost identical readings for the same sample. For example, if you have one spectrophotometer operating at a test facility in Seattle and a similarly-designed spectrophotometer operating at a facility in London, then the two instruments should be able to measure nearly identical color values for the same pressed powder sample. As long as these instruments are calibrated and set up correctly, then there should be little, if any, color value disagreement between them.

The reason this is important for pharmaceutical companies is that variations in color measurements between instruments can result in false alarms and wasted product. It can also lead to inconsistent coloration of your products, as your instruments may not apply a consistent color standard. For example, if you use two relatively similar spectrophotometer models (like the <u>UltraScan VIS</u> and the <u>UltraScan Pro</u>) to measure the color of allergy capsules at two different manufacturing facilities, you might assume that both instruments will give you consistent readings because they have similar settings. However, factors like operational inconsistencies, even between two the same model, can cause these spectrophotometers to give you two very different color readings for the same sample. When this happens, you might throw out a perfectly good batch of product because you believe that it is inconsistent or incorrect in color. Or you may believe that both batches are identical in color because both fall within the predetermined tolerance range, but instrumental inconsistency results in inconsistent color between the batches.

This is why you need to improve your color measurement methods using Hitch Standardization procedures. With Hitch Standardization, you can hitch together two of the same spectrophotometer models (which will give you the best results) or you can even hitch together two different models. As long as both instruments have the same geometry, Hitch Standardization is an option.

Full article with photos available here:

https://www.hunterlab.com/blog/color-pharmaceuticals/using-hitch-standardization-to-ensure-colorconsistency-across-pharmaceutical-manufacturing-sites/