

Spectrophotometers offer the objective data needed to assess color quality and correlate this data with EP and USP Color scale standards. Image Source: Flickr user Frédérique Voisin-Demery (CC BY 2.0)

We're seeing bad weather this year in the Pacific Northwest, with frigid temperatures that seem to have made the cold and flu season worse. As freezing rain coated the roads last week, I found myself scavenging through my medicine cabinet for something to soothe my cough. In my hunt, I stumbled across two identical bottles of cough syrup: one a vibrant shade of red and the other a yellowish-orange goo. The off-color option had, unsurprisingly, expired nearly a decade ago. Figuring out which bottle to use was a no-brainer.

Color changes in pharmaceutical solutions are often a sign of degradation, potency change, or contamination. That's why visual pharmaceutical color standards, such as EP (European Pharmacopoeia) Color and USP (United States Pharmacopoeia) Color, were developed and are now used as a common form of evaluation across the industry. These pharmaceutical color standards are helpful in <u>assessing the color quality of APIs</u>(active pharmaceutical ingredients), excipients, biological solutions, and raw materials.

But visual analysis is highly subjective and does not provided the quantifiable data need to meet quality control regulations. Instrumental analysis is necessary for quantifying color accurately and objectively.

Quantifying Data with Spectrophotometry

Spectrophotometers offer the simple yet sophisticated color analysis needed to meet industry standards. Advanced instrumentation measures the absorption and transmission values of the drug product and converts this data into <u>tristimulus values</u>, <u>such as CIE L*,a*,b* color</u>. These values can then be used to develop an objective comparison with the visual EP/USP Color scale. Using numerical data to quantify color comparisons allows for improvement in color communication

between sites and replaces vague comparisons such as "light yellow" with advanced terminology such as "near USP F" or "EP Y2"¹. This standardizes the process, allowing for better accuracy while providing the <u>validation needed to meet pharmaceutical regulations</u>.



Numerical data provides a more accurate way to measure pharmaceutical color standards and develop consistency for batch comparisons. Image Source: Flickr user vinod velayudhan (<u>CC BY 2.0</u>)

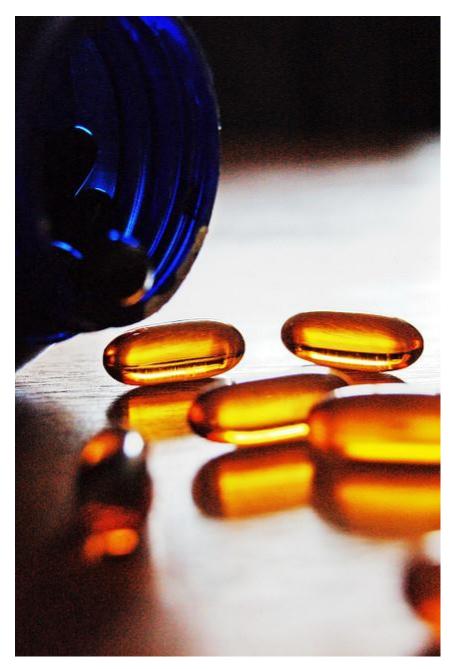
To put it succinctly, spectrophotometers provide a "quantitative method for color measurement [that] eliminates subjectivity in color assessments, removes the variability among different analysts, maximizes accuracy and precision, and can be utilized throughout the drug development process." And advancements continue to surface as we explore new methods of pharmaceutical evaluation. ².

Color Measurement of Both Liquids and Solids

But since samples vary in both color and consistency, it is important to understand the best methods of measurement for your particular sample type. Advanced instrumentation allows for the color quantification of both liquid and solid samples and utilizes precise geometric principles to provide the most accurate data.

Liquid samples vary in opacity from translucent or transparent to opaque, each affecting the transmission of light through the sample itself. Since opaque samples are impenetrable by light, they are most accurately measured using a Directional 45°/0° reflectance geometry. Translucent samples diffuse light as it passes through the sample, so depending on the level of translucency, both reflective and transmittance measurement modes are effective. Transparent samples, which allow light to pass through relatively undistorted, are best measured using transmission instrumentation³.

<u>Solid samples</u> are measured according to their pressed or powdered state. These samples often included additives such as sorbitol, microcrystalline cellulose, or dibasic calcium phosphate anhydrous. These raw materials must be carefully assessed to ensure safety, consistency, and quality control. But depending on the sample size and processing volume, many instrumentation options are available to meet the challenges of these materials.



Whether measure liquid or solid color samples, spectrophotometers offer the highest level of accuracy and versatility in color measurement instrumentation. Image Source: Flickr user herval (<u>CC</u> BY 2.0)

Versatility and Options in Spectrophotometric Instrumentation

With the varying requirements of sample types and sizes in the pharmaceutical industry, it is important to keep versatility in mind when you choose your color measurement instrumentation. HunterLab offers many spectrophotometer options, each designed for adaptable applications. With over sixty years of experience in the color measurement industry, HunterLab has created a line of products <u>specifically for pharmaceutical color standards</u> and analysis. We help our clients select the instrumentation most suited to their needs and offer unsurpassed customer service to help you make the most of your tools. For more information on HunterLab products, <u>contact us today</u>.

1. "USP and EP Color Standards", July, 2009, https://support.hunterlab.com/hc/en-

us/article_attachments/.../an20_08.pdf

- "What Color is Your Drug Solution?", <u>http://abstracts.aaps.org/Verify/AAPS2014/PosterSubmissions/T3286.pdf</u>
- 3. "Pharmaceutical Liquid Color Measurement", 2013-

2017, https://www.hunterlab.com/pharmaceutical-liquid-color-measurement.html