

The European Pharmacopoeia color scale was developed to facilitate communication regarding the color of liquid pharmaceuticals. Image Source: Pexels user bogitw

Imagine trying to describe the color of a light yellow liquid to someone across the world. What words do you use? How do you communicate the exact qualities of this particular shade? How do you describe the degree to which it differs from another, similar but distinctly different color? These are questions faced by multiple industries across the globe and specialized color indexes, such as the <u>APHA</u> and <u>Gardner scales</u>, have been developed to allow us to more easily categorize hues and share color information. Within the pharmaceutical industry, one of the most commonly used color indexes is the European Pharmacopoeia (EP) color scale, which was created to harmonize <u>liquid</u> <u>pharmaceutical</u> classification and facilitate communication within the industry.<sup>1</sup>Using a range of 37 discrete colors produced via specific combinations and dilutions of three primary color solutions, the EP scale allows industry professionals to move away from vague and imprecise descriptors to a more consistent, uniform way of identifying color quality in APIs, excipients, and any other liquid pharmaceutical products or components.

However, determining EP scale placement has traditionally relied on visual matching of a sample to a standard within the series. This process has several major points of vulnerability:

- Colors may vary between EP standard batches due to imprecise formulation or material degradation.
- Near-clear samples are often extremely difficult to match.
- Matching requires a relatively large sample volume.

• Matching relies on subjective visual assessment, which may be negatively affected by a host of factors, including viewing environment and observer <u>color vision deficits</u>.

As such, visual color matching with EP scale standards presents major risks to <u>accurate and</u> <u>consistent color assessment</u> and compromises the ability to make meaningful use of the scale. Quantitative color assessment using spectrophotometric technology allows you to overcome these limits, produce accurate, repeatable color classification, and harness the full potential of the EP color scale.



Spectrophotometric EP color classification allows for the assessment of even small liquid samples. Image Source: Unsplash user Nithya Ramanujam

Spectrophotometric EP Color Classification

Spectrophotometric color measurement easily and objectively quantifies color information while removing unstable and subjective factors that may distort results. By analyzing the transmission spectrum of the liquid and converting that spectrum to tristimulus color values, the spectrophotometer is able to discern color variations so minute they are undetectable to the human eye. At HunterLab, we have correlated tristimulus color values with the EP color standards and integrated this index in our EasyMatch QC software, giving pharmaceutical researchers and manufacturers a simple, validated method of determining EP color with extraordinary precision and detail. The advantages of spectrophotometric EP color classification using HunterLab spectrophotometers and EasyMatch QC software include:

- Eliminates subjective visual assessment and human error.
- Facilitates accurate color determination, even in small samples.
- Allows for reliable measurement of near-clear liquids that present special challenges to human visual discrimination
- Expands quality control capabilities and provides "greater insight into lot-to-lot variability and precise color tracking of multiple lots."<sup>2</sup>

The extraordinary level of accuracy spectrophotometric EP color classification provides enhances both quality control of existing liquid pharmaceuticals and evaluation of new pharmaceutical formulations. As biotech researchers Karin Lucas and Kevin Maloney note, HunterLab's EP color measurement system is particularly useful in assessing color behavior over time, allowing for "a more quantitative and sensitive monitoring of color change … than traditional visual appearance testing."<sup>3</sup>



Objective color analysis creates a common language within the pharmaceutical industry, facilitating communication amongst stakeholders. Image Source: Pexels user Eric Bailey

## Facilitating Color Communication

The EP color scale was originally designed as a kind of communication mechanism that would allow color information to be easily shared within the pharmaceutical industry. Spectrophotometric EP color classification gives you the ability to realize this goal with greater ease than ever before. Because spectrophotometers measure color the same way every time, regardless of operator or location, you are able to produce consistent EP color scores across your supply chain based on objective analysis, facilitating information sharing and ensuring that all stakeholders are on the same page. This is especially critical in a time of increasing globalization of research, testing, and manufacturing practices, as a <u>common chromatic language</u>allows actors in disparate locations to meaningfully communicate with each other regarding product formulation and behavior. The result is an expanded ability to work harmoniously to produce the highest quality pharmaceutical products.

## HunterLab Quality

HunterLab has been the world leader in spectrophotometry for over 60 years and is committed to continuously expanding the possibilities of color measurement. Our versatile range of

spectrophotometric instruments and sophisticated software packages are designed to meet the unique needs of the pharmaceutical industry and enhance your color quality control at every stage of the research, development, and manufacturing process. <u>Contact us</u> to learn more about our products and dedicated customer support services.

- 1. "European Pharmacopoeia 4," http://www.ut.ee/ARFA/fkeemia/EP4\_selgus\_varv.pdf
- "What Color is Your Drug Solution? Quantitative vs. Qualitative Color Measurement," June 4, 2014, http://www.business-review-webinars.com/webinar/Pharma/What\_Color\_is\_Your\_Drug\_Solution\_Quantitative\_vs\_Quali

tative\_Color\_Measurement\_-t7H2NPWk/registration

3. "Methods For Inhibiting Yellow Color and Peroxide Formation in a Composition," January 20,

2011, http://www.google.com/patents/WO2011008770A2?cl=en