

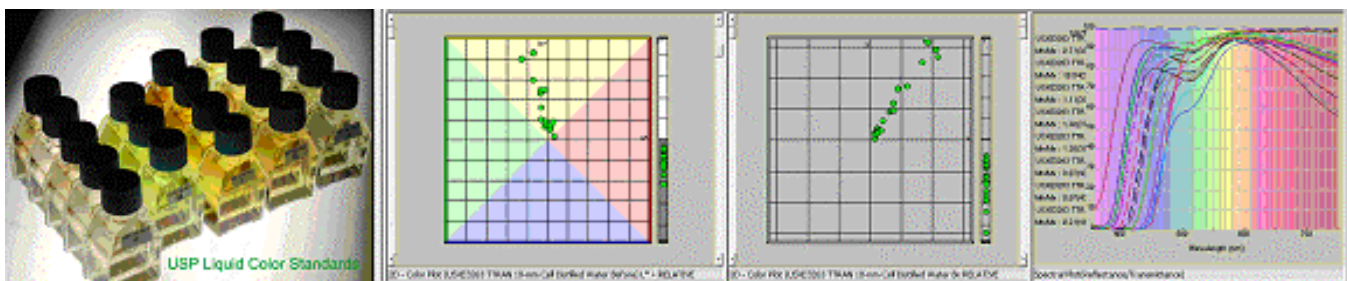


USP and EP Visual Color Standards

The USP and EP Color Standards are visual color standards, intended to improve color communication between sites by defining a sample color as being close to physical liquid standard (“near USP F”; “near EP Y2”) rather than using words. (“light yellow”).

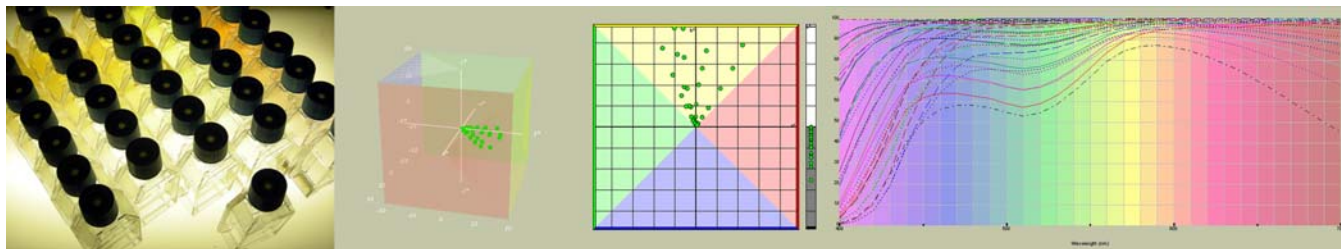
The USP - United States Pharmacopoeia visual color standards consists of 15 matching liquids color standards (A-T) derived from 3 primary solutions (cobaltous chloride, ferric chloride and cupric sulfate) mixed with water in various ratios.

Reference for USP Color Standards: USP-24 Monograph 631 Color and Achromaticity, United States Pharmacopoeia Inc., Rockville MD USA (2000: 1926-1927) NET: www.usp.org.



EP - European Pharmacopoeia Color is a similar visual liquid color scale used in the pharmaceutical industry. It consists of 3 primary color standard solutions (yellow, red and blue) that are combined with hydrochloric acid to make 5 standard color solutions - B (brown), BY (brownish-yellow), Y (yellow), GY (greenish-yellow) and R (red) that are subsequently diluted with hydrochloric acid (10 mg/l) to make 37 reference EP liquid color standards - 9B, 7BY, 7Y, 7GY and 7R.

Reference for EP Color Standards: European Pharmacopoeia Method 2.2.2 Degree of Coloration of Liquids, European Pharmacopoeia, Strasbourg, France (1997: 15-16) NET: www.phEur.org



Description of Instrumental Correlation to USP and EP Pharmacopoeia Color

USP Monograph 1061 Color – Instrumental Measurement references the use of CIE L^* , a^* , b^* color measurement to quantify colors precisely and objectively.

When measured, the 15 USP Liquid Color Standards are spread along the + b^* yellowness axis with little tint runs of red and green.

The 37 EP Liquid Color Standards are spread along the + b^* yellowness axis in 5 tint runs of red and green radiating out.

The best method for a USP or Color instrumental correlation is to think of these liquid color standards as isolated points in color space with the task being to find and report the USP or EP color standard nearest to the sample color. Correlating the instrumental measurement to the USP/EP Color Scales allows the use of colorimetry to quantify the color and communicating in the USP and EP reporting numbers.

Typical Measurement Method for USP or EP Pharmacopoeia Color

1. In an EZMQC job, the user selects “USP-10mm [D65/10]”; “USP-20mm [D65/10]”; “EP-10mm [D65/10]” or “EP-20mm [D65/10]” in the Color Data view, matching the path length of cell being used and the need to report USP and/or EP Color.
2. A sphere instrument like the UltraScan Pro, UltraScan VIS or ColorQuest XE is standardized in the TTRAN LAV UV Filter Nominal transmission mode using a 10-mm or 20-mm cell filled with distilled water.
3. It is advised that the user read back the cell filled with distilled water as an OQ (Operational Qualification) step with a reading of $L^* = 100.0$, $a^* = 0.0$, $b^* = 0.0$ D65/10 and USP-10mm [D65/10]; USP-20mm [D65/10]; EP-10mm [D65/10] or EP-20mm [D65/10] Color = “Water” expected to be displayed.
4. If a USP or EP liquid color standard near the product color is available, the user could read this as an Application diagnostic, expecting it to read as assigned and the same over time.
5. The client standard or sample is then read, the corresponding L^* , a^* , b^* calculated and the nearest correlated USP-10mm [D65/10] or USP-20mm [D65/10] rating reported based on a minimum color difference relative to the color of the liquid USP color standards.

This will allow the USP or EP reporting requirements. To determine small lot-to-lot color differences use CIE L*, a*, b* differences, or for clear liquids, Yellowness Index per ASTM E313 or APHA.

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