

Sensegood spectrophotometer for color measurement and consistency control in pharmaceutical industry – pills, drugs, liquid drugs, powders, Active Pharmaceutical Ingredients (API), and medicines



Color measurement and management in pharmaceutical products – Photo: colorful pills.

Colorants are frequently used in pharmaceutical industry mainly for the following reasons:

- to provide physical and chemical protection to the drug
- to mask the taste or color of the drug
- to control the release rate of the drug from the tablet
- to provide unique identity to a commercial product
- Coloring tablets have aesthetic value and can improve tablet identification, especially when patients are taking a number of different tablets [1]

Colorant examples:

FD & C red no. 3, no. 20, FD & C yellow no. 6, FD & C blue no. 2, D & C green no. 5, D & C orange no. 5, D & C red no. 8, caramel, ferric oxide, are most common.

Purpose of Color Measurement:

- Color change in a pharmaceutical product is an indication of:
 - a. Chemical and physical degradation [2]
 - b. Process variations – improper drug formulations
 - c. Impurity presence
 - d. Issues with raw materials
 - e. Counterfeit [3]
- Research and development
- Analytical and physical testing
- Pre-clinical testing
- Stability tests – shelf life contamination study [4]
- Scale-up

Psychological effects of color:

Unique color and shape of the pill determines sales percentage. Study on same drug pills by different manufacturers implied that pills had higher counting unit sales for manufacturer which used unique color and shape for the pill. Established fact is; branded generics with specific color and shape have higher market shares than plain, white tablets. [5]

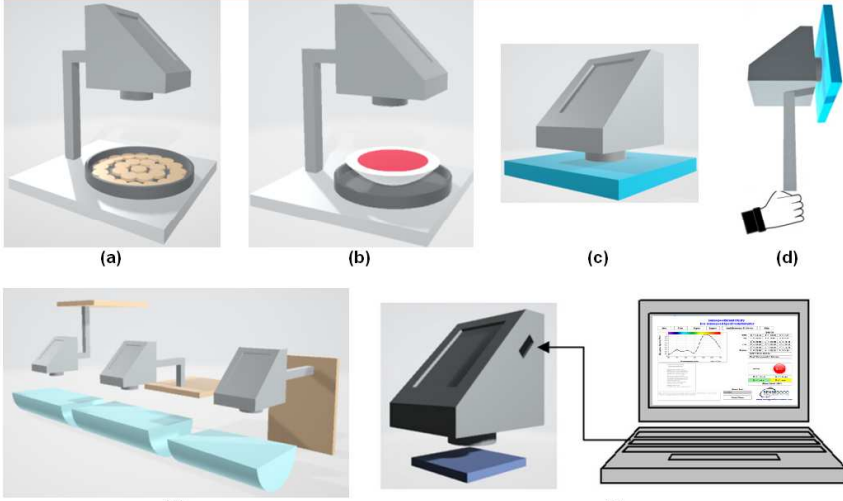
Dr. Aaron S. Kesselheim, Harvard Medical School, and principal investigator of the study, explains: “Pill appearance has long been suspected to be linked to medication adherence... We found that changes in pill color significantly increase the odds that patients will stop taking their drugs as prescribed.” The study (study period:

2001-2006) was carried out on huge mass of 61,522 patients out of which 11,472 stopped medications due to appearance change in pills. [6] When customer sees a pill in different color than the one being regularly taken, he immediately believes it to be counterfeited. This is why color measurement and control is necessary toward achieving the consistency.

When it comes to pharmaceutical packaging, color choice is based on visual appearance. Just like the color of a medication is believed to have an impact on the consumer's mind, similarly the pharmaceutical dyes used in packaging have an effect that shapes the consumer's expectations. [7]

Color is associated with human emotions hence this attribute is used to study market patterns. Drugs claiming to be innovative or cutting edge are likely to be produced in different colors than ones positioned as reliable. [8]

SENSEGOOD SPECTROPHOTOMETER - UNIVERSAL (REFLECTANCE)



- ✓ Benchtop/ Tabletop: (a) (b)
(Rotating sample platform)
- ✓ Handheld/ Portable: (c) (d)
- ✓ Online/ In-process: (e)

- ✓ Solid: (a) (c) (d) (e)
- ✓ Liquid: (b) (e)
- ✓ Paste: (b) (e)
- ✓ Powder: (a) (b) (e)

- ✓ Contact measurement: (c) (d)
- ✓ Non-contact measurement: (a) (b) (e)
(Adjustable height)

- Works with:
- ✓ 5V adapter (cell phone charger)
- ✓ Power bank
- ✓ Computer/ Laptop (f)

- ✓ Averaging
- ✓ Auto repeat measurement mode
- ✓ Color match percentage
- ✓ Color indices (whiteness, yellowness, ...)

- ✓ SensegoodSmart
– computer interface software utility

Instrumental color measurement:

In the process of visual color match; there are factors like eye fatigue, aging of the eye, stress, individual's different expressive perception toward color, and light source that affect the color match decision. Hence, it becomes difficult to make decision of accepting, reprocessing or rejecting the sample based on visual match. And this directly hampers the quality of the final product. While on other hand there are advantages of instrumental color quality control as it provides results with same accuracy, consistency and reliability. [9] It provides numerical color data, a common color language amongst researchers. It eliminates subjectivity in color assessments, eliminates the variability among different analysts and maximizes precision.

Sensegood spectrophotometer for color quality and consistency control in pharmaceutical industry:

Sensegood Spectrophotometer offers color measurement technology to the pharmaceutical industry and research community and is an essential tool for quantitative and qualitative analysis. From raw material to final product, it comprehensively evaluates the color attributes of various samples, including solids, powders, pills, pastes, and liquids. Sample can be non homogeneous with different shape and size. Sensegood spectrophotometer has rotating sample platform with large viewing area (sensor's field of view). It takes multiple measurements over number of rotations and generates average result representing the sample's color. As a result, consistency can be maintained and quality standards can be met with less waste, time, and effort.

Sensegood spectrophotometer helps in picking up even the slightest color difference over the production batches. It helps in finding difference between two colors and shows result in percentage match.

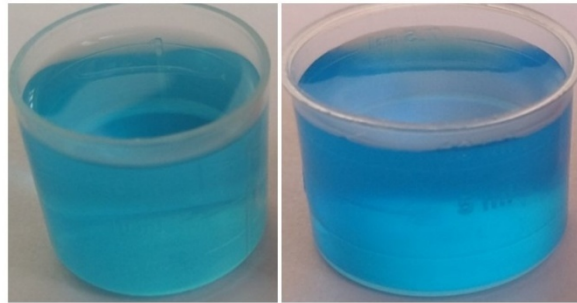


Reference: L* = +36.63, a* = +40.79, b* = +20.47	Sample: L* = +45.11, a* = +48.32, b* = +31.52	Reference: L* = +74.49, a* = +3.59, b* = +8.86	Sample: L* = +68.85, a* = +6.38, b* = +4.49
$\Delta L^* = +8.48$, $\Delta a^* = +7.53$, $\Delta b^* = +11.05$, $\Delta E^* = 15.83$ Sample is Brighter, Redder and Yellower than reference. Alarm limit = 92%, MATCH: 84% Alarm triggered as Match % is below user set threshold of 92%		$\Delta L^* = -5.64$, $\Delta a^* = +2.79$, $\Delta b^* = -4.37$, $\Delta E^* = 7.66$ Sample is Duller, Redder and Bluer (less Yellower) than reference. Alarm limit = 91%, MATCH: 92% Sample is within desired color tolerance set by user	

Sensegood Spectrophotometer for color quality and consistency control in pharma pills and powders

Photo: Right color indicates tight process control and right proportion of ingredients for right drug formulation. Color consistency in pharmaceutical products is essential for better branding and market acceptance. Establish color tolerance using Sensegood spectrophotometer to ensure batch to batch color consistency. In photo: Measured color difference is presented in terms of matching percentage in pills and powders. Standard reference color can be saved and recalled anytime to compare it with sample. If matching is below user set threshold, it warns by providing audible alarm and indication on LCD. Sensegood spectrophotometer provides information regarding color component differences in between sample and reference. This information assists in reprocessing for color adjustments.

Photo: Ensure color consistency in liquid drugs using Sensegood spectrophotometer. Color difference measurement makes even more sense than absolute color measurement. In photo: Color difference in brilliant blue of dextromethorphan hydrobromide syrups.



$\Delta E^* = 9.17$, Alarm limit = 94%, MATCH: 91% Alarm triggered as Match % is below user set threshold of 94%

**Sensegood Spectrophotometer for color quality and consistency control in liquid drugs.
Color difference in brilliant blue of dextromethorphan hydrobromide syrups**



Whiteness Index – Stensby: 86.23	Whiteness Index – Stensby: 77.58
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API powder: $L^* = 84.28$, $a^* = 2.05$, $b^* = 3.23$ Whiteness Index – Stensby: 80.74

Sensegood Spectrophotometer for color quality and consistency control in pharma pills and powders

Photo: Apart from absolute color and color difference measurement, Sensegood spectrophotometer is also equipped with analytical algorithms for various color indices like whiteness index, yellowness index, including many other indices. Color index value is the overall numerical representation of sample's color characteristics. In photo: Measurement of whiteness index in white pills and white active pharma ingredient (API) powders. Higher the value of whiteness index, sample's color is toward bluish white. On the contrary, lower the value of whiteness index, sample's color is toward yellowish white.

Measured L^* , a^* , b^* color space values indicate light, redness/greenness and yellowness/blueness; useful in determining quality of white, red-brown, green, yellow, or blue textured products. Sensegood spectrophotometer also evaluates color in terms of chroma C^* and hue H° along with various other color parameters.

Do more with Sensegood spectrophotometer:

Sensegood spectrophotometer incorporates continuous auto measurement mode. In this mode, it wakes up at user selectable intervals, takes measurement, compares the sample color with the saved reference, displays percentage match, and alarms to the operator with beeping sound in case if the matching percentage is below preset threshold. It has provision for averaging option in normal mode as well as in auto repeat measurement mode.

Measured color is also represented as reflectance graph, peak wavelength and color temperature on color touch LCD. Sensegood spectrophotometer is non-messy non-contact type instrument which has benefit of measuring sample's color from a distance. Because of this, sensor remains scratch proof enabling long life in retaining calibration. Non-contact measurement avoids any sample contact and contamination on sensor measuring surface. Hygiene is maintained, as non-contact measurement avoids any food contact and bacterial accumulation on sensor measuring surface. Sensegood spectrophotometer is the versatile device that is engineered to work as handheld/portable, benchtop/table-top or in-process/online color measurement instrument.

SensegoodSmart utility:

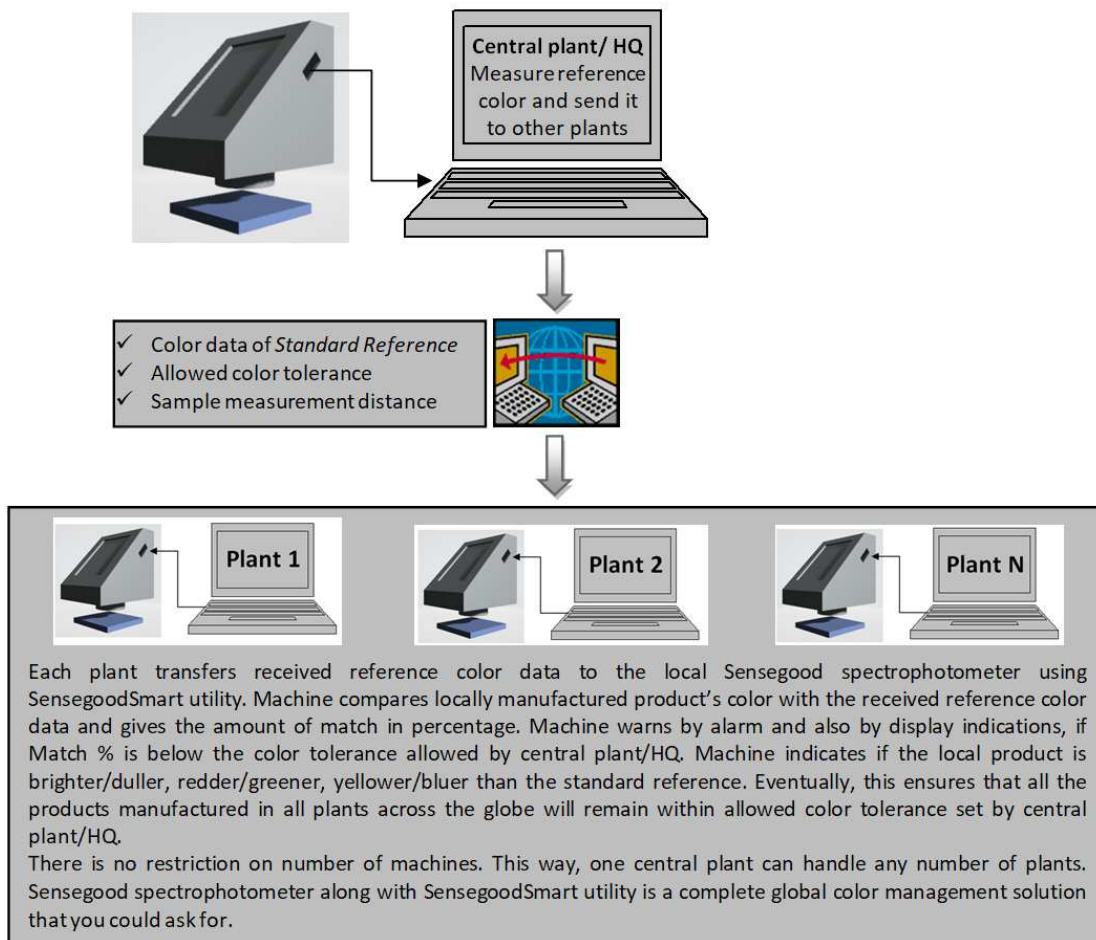


Photo: SensegoodSmart utility for color management across multiple production plants. Apart from this, SensegoodSmart utility enables user to store unlimited number of references to the computer. Any desired reference can be recalled and downloaded to Sensegood spectrophotometer whenever required. The utility provides all color related analytical information on single screen. This feature is even more desirable when using Sensegood spectrophotometer for in-process/online applications.

Sensegood spectrophotometer provides computer interface software *SensegoodSmart* which lets you to convey numeric color data across all production plants that may be located at multiple places across the globe. Each production plant uses Sensegood spectrophotometer to compare color attributes of the product manufactured in their plant with the numerical color information received from central plant or management. This enables them to reproduce each product consistently across all the plants. This feature is highly desirable for wide spread industry with plants at various places. It also assists in color consistency in packaging material supply chain.

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