PHARMACEUTICAL INDUSTRY COLOR CONTROL

THE COLOR OF QUALITY

The appearance of a product greatly influences its sale ability and has tremendous influence on choice. Wrongly colored products may lead to adverse consumer reaction as they appeal to the emotional senses and touches of a buyer in a very special way. For example, colors of consumer goods influence consumer acceptance and the act of putting the product into the shopping cart. In the food industry, color indicates freshness and ripeness of a food product and is often deem as a quality indicator.

Similarly for pharmaceutical industry, color is perceived and documented for special reasons. Color evaluation is practised widely in laboratory and manufacturing environments to identify color attributes and inconsistencies in drugs and medications. Companies that produce the exact color will know that color is an integral part of long term business success and would take quality control seriously. With the current technology, many pharmaceuticals have found ways to improve testing and save valuable time and money when it comes to color control and evaluation.

Color Control

It is an important criteria in the production of pharmaceutical and personal care products. It is no surprise that the ingredients used in making pharmaceuticals are highly regulated, requiring a series of tests and quality control steps to ensure that consumers are receiving safe and correct drug dosages.

In the pharmaceutical sector, color evaluation practices are widely deployed in laboratory and manufacturing environments to accurately communicate color attributes and inconsistencies in samples and ensure color quality standards are met.

The quality and safety of drugs are of high focus by regulatory authorities worldwide. To fulfil the high requirements of regulatory standards like the United States Pharmacopeia (USP), European Pharmacopeia (EP) and all other Pharmacopeias, accurate and reliable color measurement instruments are needed.

Visual Assessment

Color theory may seem complex but in reality the human eye can detect minute differences quickly and accurately. Unfortunately, individual observers do not always agree on these differences, thereby leading to miscommunication. One can remember only general categories of color, making it almost impossible to make color reference to a non-existing sample.

The interpretation of color is subjective and is easily influenced by factors which cannot be controlled easily. The size of sample, age and lighting conditions are just a few of the factors that can affect a person's judgement. Most industries rely on the acquired skill of trained technologists to detect minute differences in the color of finished products. Even so, problems still arise when trying to communicate a precise description of a color between various departments or groups of people.

Appearance Measurement

When light strikes an object, it is transmitted, scattered, reflected or absorbed. The resultant effect of this light determines the color of a material which depends on the combined effects of the viewing angle, light source, lighting quality, background and size of the object.

For pharmaceutical preparations, color can be classified into three categories – opaque, translucent or transparent. In color perception, color is reproduced when light interacts with an object, an observer and a light source.

The Commission Internationale del'Eclariage (CIE) is an organization known for their works in color science, specifies the use of standard illuminants and a standard observer to obtain CIE tristimulus. Tristimulus values is a set of imaginary red, green and blue primaries that are converted into color spaces to make color data easier to quantify.

CIE L*a*b* and CIE LCH color spaces are widely adopted in the several industries for color control and measurement.

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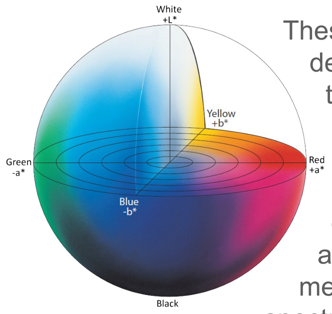

These color spaces measure the degree of lightness (+L*) and the degree of redness (+a*) or greenness (-a*) and degree of yellowness (+b*) or blueness (-b*). With color spaces, color can be communicated precisely and meaningfully using color measurement instruments such as a spectrophotometer.

Spectrophotometers

Spectrophotometers provide precise color information or the “fingerprint” of a color. These instruments measure the spectral reflectance or transmittance of a sample across the visible wavelengths from 400nm to 700nm and are recommended for applications where strict color specifications are employed or where investigative works are required. Advancement in optics and color technologies has made color measurement error free by non-experts.

Color measurement can be taken easily, quickly and without mistakes by anyone even for first time or occasional users. With built in calibration systems, setting up the instruments is fast and easy. An integrated system allows transmittance and reflectance measurement for all kinds of medical samples.

The use of spectrophotometers can be found in pharmaceutical companies due to several benefits for a variety of applications. It can be used for many purposes such as to ensure that products adhere to quality standards. Pills, for example, need to have unique shapes and colors so they will not be mistaken for other medicines. Another use is to ensure that the color is consistent in the dosage. If a color is incorrect, it can change the outcome of the final product and cause wastage at the production line.

Applications

Measuring Color with Accuracy for R&D and Batch Control

Spectrophotometers are very precise instruments that are used to analyse the color as well as the appearance of an object. They can be in different types each with specialized purpose. Bench-top spectrophotometers for instance are used in the measurement of solids, powders, creams and even liquids form. They are in widespread use in pharmaceutical companies due to its versatility in sample measurements. Spectrophotometers ensure that a product's color matches specifications by evaluating and expressing it in numerical terms. Manufacturers can control pigments and hues in pills, powders, liquids, and other pharmaceutical products more easily with the color information provided by the spectrophotometer. This extreme accuracy reduces wastage and outputs higher quality products with greater efficiency, which will increase profits.

Spectrophotometer Solutions for the Pharmaceutical Industry

Many pharmaceutical laboratories use bench-top spectrophotometers to evaluate the effects of ingredients in a medicine. Assays are created on a sectioned plate, and each section is administered with a different amount of the active product ingredient. A dye that activates when cells in the assay incorporate the ingredient is also administered to each section of the plate. Using the bench-top spectrophotometer, scientists and researchers can easily measure numerically the effect the ingredient has on a cell by measuring the color of the dye in each section.

Ensuring Clarity in Transparent Ingredients

Just like the atmosphere, haze can create a cloudy appearance on objects. This cloudiness makes the objects appear lighter and distorted, creating problems for manufacturers having to meet certain quality standards for their products.

A hazy appearance on chemical occurs when irregularities in the substance cause light to scatter. If light scatters when it hits or passes through a solution, haze can appear and the clarity of the solution is compromised. This lack of clarity usually affects transparent liquids and is highly problematic for manufacturers.

Measuring Haze

Haze can be controlled and minimized using appropriate instrumentation. Color measurement technology not only evaluates the color, but also the lack of color in a liquid. When haze is problematic in transparent chemical, a transmission spectrophotometer or haze meter should be used for process control.

Spectrophotometers, often used in conjunction with QC analysis software, generate comprehensive data on the clarity of the liquid and the amount of haze in its appearance. This allows users to pinpoint the origin of the haze and take corrective action immediately.

A standard haze value should first be defined to ensure each batch of liquid maintains consistency and clarity. For example, standard percentage Haze value between 0% and 30%. If the sample percentage Haze value is greater than 30%, the sample will be rejected. Each sample may also be evaluated using a spectrophotometer to identify any cloudiness in the liquid, the amount of haze (percentage Haze value) in its appearance, and if these values are within the established standard. With this data, corrective action can effectively be taken before a bulk production run is performed and documented for future batches.

By identifying the problem in advance, rework and product rejects are prevented. To effectively evaluate transparency and haze in samples, the spectrophotometers are therefore recommended.

*Picture Source from Mettler Toledo