Pharmaceutical grade starch is a commonly used excipient in the formulation of medications. Image Source: Flickr user CIAT

American consumers are more aware than ever when it comes to the ingredients we put into our bodies. Gluten free, peanut free, dairy free, etc.; the list goes on and on. While food packaging clearly labels these ingredients, many consumers overlook these additives in the drugs and medications they take each day. However, the ingredients found in today's pharmaceuticals are also subject to strict regulations to ensure safety and quality and require accurate analysis to meet industry standards.

Food grade additives are a commonly found in many of the drugs and medications we use on a regular basis. For example, pharmaceutical grade talc and/or starch are often used to create a base for active ingredients and these fillers comprise a large percentage of the product we ingest. Product color and purity are a major concern when it comes to these additives and color standards for pharmaceutical grade starch and talc are necessary to achieve desired results. Color measurement instrumentation is an important tool when it comes to quality control. Spectral analysis provides the information needed to meet industry standards and monitor color changes in formulations.

Pharmaceutical grade starch is an abundant natural resource found around the world. Monitoring quality and color play an important role in drug formulation and consistency. Image Source: Flickr user CIAT

Measuring Pharmaceutical Starch Quality

Pharmaceutical grade starch is a popular ingredient for use as both a binding agent in hard tablets as well as disintegrating agent in orodispersible formulations. An influx of pharmaceutical grade starch production is inundating the industry as reliable filler for drug use in today's market. This product is sourced from around the globe and value can vary depending on production quality. One indication of superior quality is in the white appearance of starch, making it a preferred choice of filler for use in color-coded medications where specific color matching is necessary. Though white is classified into one color category, there are many variations within that range. Pure white, or extra-white is the most desirable and marketed as the highest quality product. Measuring pure white relies on spectrophotometric technology, which can differentiate even the slightest variations in hue.

Spectrophotometers measure color value to determine purity by the degree of whiteness. Pure white can be quantified numerically depending on the color scale being used. This means that if there are any impurities in the starch, they will affect its color and be measured as a different color value. color scale data can then be stored and used to develop a pass/fail tolerance.

The ability to monitor changes in color values allows pharmaceutical companies to create color standards for pharmaceutical grade starch and select only the highest quality products for drug formulation. Monitoring color standards by degree of whiteness is an efficient and effective method for evaluating pharmaceutical grade starch and ensuring color quality in product formulations.

Spectrophotometers closely monitor powder composition to provide quantitative data in color formulizations. Image Source: Flickr' user shadphotos

Monitoring Color Changes in Formulation

Pharmaceutical grade starch is an abundantly available natural resource and preferred excipient for drug delivery systems in pharmaceutical solid dosage forms[1]. It is commonly used as a filler, binder, or coating in the drug manufacturing industry. Both the physical properties and white coloring of pharmaceutical grade starch make it a desirable choice in color formulations, where color consistency is of upmost importance. There are several factors to consider when blending a powdered excipient like starch with an API (active pharmaceutical ingredient). Spectrophotometers are required to closely monitor the powder composition and provide a quantitative analysis of the sample. This information can then be stored with advanced software capabilities and provide the data needed to achieve **color consistency and repeatability from batch-to-batch**.

While excipients are a necessary part of drug formulations, the structure and powder-like quality of pharmaceutical grade starch can create many challenges when evaluating whiteness and/or monitoring changes in color formulations. Loose powders present various difficulties in color analysis due to their non-uniform texture. Starch powder consists of many small particles that are highly susceptible to light trapping, shadowing, and ambient light interference, which can lead in inconsistent color measurement results[2]. Therefore, samples must be carefully prepared and measured. The UltraScan Vis offers an optional reflectance shelf that can mounts so that powder filled cups or pressed plaques can be presented at the reflectance port

Choosing the Right Instrumentation

Spectrophotometric analysis is ideal for monitoring color standards in pharmaceutical grade starch. These tools offer a non-destructive evaluation of color and can be utilized for on-line measurements where continual monitoring of color is necessary to maintain consistency. Once formulations are pressed into plaque form, spectrophotometric instrumentation can be used to measure these samples using specific viewing angles and geometric principles to obtain the most accurate and reliable information.

HunterLab spectrophotometers have been created to meet the specific needs of the pharmaceutical industry. Our spectrophotometers provide a low-cost alternative to other methods for color standard analysis and monitoring the blending and compression of pharmaceutical powders and plaques. Our staff is highly knowledgeable in the color measurement of pharmaceutical products and we back our products with unsurpassed customer support. Contact HunterLab to learn more about our options in pharmaceutical color measurement instrumentation.

1. "From native to multifunctional starch-based excipients designed for direct compression formulation", June 3, 2013,

   http://onlinelibrary.wiley.com/doi/10.1002/star.201200297/full

2. "Measuring Loose Powder with with UltraScan® VIS, https://www.hunterlab.com/mm-5039-

   measuring-loose-powder-with-ultrascan-vis.pdf