When I make a trip to the drugstore, I don't usually struggle with the choice between name-brand medication and generic drugs—I tend to base my choice on the active pharmaceutical ingredients (APIs)[1] listed on the package.

But only recently have I come to realize that the excipients listed on a drug's packaging also play an important role. In fact, as my clients in the pharmaceutical industry have been happy to explain, manufacturers must rely on the analysis of both drugs and excipients in solid state to ensure the quality and efficacy of their products.

Fortunately—as *I* was happy to explain to my clients—spectrophotometry can help with this process.

Solid state excipients consist of compressed plaques and loose powders which account for the bulk of ingredients needed for the formulation and effectiveness of today's pharmaceutical products. Image Source: Flickr user Axel Naud (**CC BY 2.0**)

The Role of Excipients in Pharmaceuticals

Pharmaceutical manufacturers can attest to the fact that excipients play a variety of important roles in the formulation of medications. While some are used specifically to help transport the active drug effectively to the proper area of the body, others might be used for suspension and delayed release

in order to minimize irritation of the GI track—or designed to dissolve rapidly, allowing the API to reach the bloodstream as quickly as possible.

Measurement of soluble powders and provide the data needed for formulation quality and product effectiveness. Image Source: Flickr user Joey (CC BY 2.0)

Of course, that's not the end of it. Excipients also function as a way to preserve the stability of the drug and increase its shelf life. They can be beneficial in drug identification and serve as a way of improving both taste and appearance—a necessary consideration if you hope to promote consumer acceptance[2].

Spectrophotometers are an important part of this evaluation and formulation process. These instruments give you the ability to quantitatively analyze excipients, and provide a tool for color control, stability testing, and purity analysis.

Color Measurement in Pharmaceutical Manufacturing

Color measurement data can be used to monitor excipients both prior to formulation and throughout production. But from loose powder to granulation and compression, it is important to use the correct measurement methods to ensure the accuracy of your data. Variations in texture and reflectance value will require different measurement calculations to ensure safety, consistency, and effectiveness.

Loose powders such as pharmaceutical grade talc, for example, can present challenges in purity analysis. Spectrophotometers can evaluate the chemical purity of excipients by quantifying color changes that otherwise go undetected by the human eye. This color measurement data can be used for continual analysis throughout production to ensure stability and monitor sample degradation.

Talc is a common excipient used in pharmaceutical production. Monitoring the whiteness value with spectral technology provides the data needed for purity analysis and safety. Image Source: Flickr user Austin Kirk (**CC BY 2.0**)

Advanced spectrophotometers are designed specifically to quantify such low-level changes—changes which can have an insurmountable effect on product quality. Color measurement data is essential both for formulation accuracy and to ensure safety and quality. And at *all* stages of pharmaceutical production, spectral analysis is necessary to meet strict regulatory standards.

Color Analysis Options for Drug Excipients

There are a wide range of color measurement instrumentation options available for the analysis of drugs and excipients in solid state. Choosing a spectrophotometer requires a basic understanding of technology as well as of your industry's specific needs. At HunterLab, we specialize in pharmaceutical analysis and understand the challenges that accompany product formulation, purity evaluation, and stability monitoring. From plaques to powders, and throughout the compounding process, our instrumentation is specifically designed to monitor every stage of production.

Many of the world's leading pharmaceutical manufacturers rely on HunterLab spectrophotometers to ensure the quality and consistency of the excipients used in their products and throughout their supply chain. To learn more about our line of spectrophotometers, or for help in choosing the right option for your needs, **contact us today**.

1. " Active Pharmaceutical Ingredients Explained", January 6,

   2013, **http://www.mdtvalliance.org/active-pharmaceutical-ingredients-explained/**

2. " Overview of pharmaceutical excipients used in tablets and capsules", October 24, 2008, **http://drugtopics.modernmedicine.com/drug-**

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