Spectral analysis is one of the most common methods of analysis is pharmaceutical testing. UV-visible spectrophotometry can identify organic compounds and quantify data that conveys information about pharmaceutical stability. This economic and reliable method of analysis provides a qualitative assay that is valuable in maintaining drug performance and safety.

The Importance of Drug Stability

<u>Pharmaceutical stability</u> refers to the capability of specific drug substances to maintain an established standardized level of potency and purity for a specified period of time. Sustaining these elements is important for both performance quality and patient safety. Testing the chemical, physical, and microbial properties of pharmaceutical compounds are all important in keeping this balance and ensuring desirable results. Spectral analysis is an essential tool when comes to pharmaceutical analysis and maintaining prescription drug quality and safety.

UV-visible spectral analysis can measure the amount of ultraviolet or visible radiation that is absorbed by a specific compound, allowing for differentiation and quantification of pharmaceutical formulations. This information can be used to monitor drug potency and <u>detect impurities in prescription drugs</u>. Continual monitoring assists in formulating the precise drug dosages and helps maintain consistency in pharmaceutical products. Spectral analysis provides a rapid and non-destructive method of evaluation that can be used in any type of laboratory setting, making it a top choice for both large pharmaceutical manufacturing companies as well as small pharmaceutical applications. Using this technology is also imperative during the formulation process for monitoring the quality and <u>purity of prescription drug additives</u>, as well as active pharmaceutical ingredients (APIs).

Monitoring Degradation

Drug formulation can greatly affect the rate of degradation in pharmaceutical products. <u>Continual monitoring</u> <u>of APIs is essential for maintaining drug effectiveness</u> and plays and important role in both drug formulations, where drug solutions degrade much faster than in their solid state, and in monitoring shelf-life quality.

Although drug development and formulation are important, monitoring prescription medications after production is equally important for providing both safe and effective drugs to patients. Stability testing requires spectral analysis to monitor drug formulations of finished product beyond the laboratory setting. Many pharmacies rely on spectrophotometric technology for continual analysis of chemical, physical, and microbial changes that can occur in prescription drugs as they await utilization. These changes often present problems with drug potency and effectiveness as well as contamination and safety issues. These changes can include formulation degradation, disintegration and dissolution, microbial contamination, and loss of package integrity. All of these factors can be monitored and regulated using spectral analysis.

Regulatory Standards and Instrumentation

Prescription drugs and drug-related formulations are strictly regulated by government agencies. The <u>Food</u> and <u>Drug Administration (FDA)</u> is responsible for ensuring that prescription drug formulations meet the API standards for effectiveness and safety. These standards require the use of analytical methods of testing for quantification of APIs and determination of impurities which affect the integrity and safety of the pharmaceutical product. These regulations also require the continual monitoring of drug stability and degradation for continued compliance of safety and quality standards.

Spectral analysis is an approved method for meeting these requirements and is one of the most commonly used evaluative tools in the pharmaceutical industry. Spectrophotometers are both rugged and portable,

making them the ideal instrumentation for many pharmaceutical analysis applications. This technology offers a highly versatile method for determining the many various analytical procedures required for drug stability testing. Spectral analysis instrumentation is available in a variety of options designed to meet every budget and need.

Full article with photos available here:

https://www.hunterlab.com/blog/color-pharmaceuticals/keeping-the-balance-stability-testing-in-pharmaceuticals-with-spectral-analysis/