Stability testing is an essential part of the drug approval process, but it also plays a critical role in helping pharmaceutical companies determine which drugs are most likely to be commercially viable. Image Source: Pexels user pixabay.com

The development of new medications is an exciting process that opens up new possibilities for preserving health and improving the quality of life. Due to the high stakes of pharmaceutical development, it is also an exacting, time-consuming, and labor-intensive process, as new medications must be subjected to rigorous testing to determine efficacy and ensure that drugs conform to strict performance standards prior to release. However, drugs don't just have to perform in clinical trials immediately after manufacturing, they also have to remain potent and safe over time to be useable in the real world. As such, stability testing is one of the prime areas of investigation during drug development, allowing researchers to observe the stability of pharmaceuticals in response to stressors to determine chemical behavior over time.

While in the long term, drug stability testing gives pharmaceutical companies the ability to establish appropriate shelf-life, storage, and usage instructions for end users, it also does something else: it helps you predict which drugs will be commercially viable early on in the development process, allowing you to make informed decisions regarding resource allocation. "I've worked on oncology drugs that were shown to be very efficacious in the clinic, but they were removed from development because of stability reasons, says Dr. Richard Ladd, senior director of pharmaceutical and life sciences marketing at Waters. "So early on you do rapid testing to predict the stability and pick winners."[1] UV-Vis spectrophotometry offers a fast, economical, and accurate method of assessing drug stability indicators at all stages of drug development and manufacture, giving pharmaceutical companies the critical data they need to predict product viability.

UV-Vis spectrophotometers allow researchers to evaluate key quality parameters to ensure that a medication is safe both at the time of manufacture and for future use.
Image Source: Flickr user Charles Williams

UV-Vis Drug Stability Testing

UV-Vis spectrophotometry quantifies the amount of UV or visible light absorbed by a compound, allowing researchers to objectively assess a number of key stability indicators, including determination of **active pharmaceutical ingredients (API)** and identification of contaminants. The extraordinary insight made possible by UV-Vis spectrophotometers has made them an essential part of quality control assessment during the manufacturing process and today an increasing number of pharmaceutical companies are **integrating UV-Vis instrumentation throughout drug production**.

The analytical abilities that make spectrophotometry valuable for quality monitoring during manufacturing also make it ideal for many forms of stability testing. While a drug may be correctly formulated and stable at the time of manufacture, **environmental stressors such as light**, temperature, pH changes, oxidation, and hydrolysis can cause chemical changes that destabilize the chemical structure of the medication.[2] As noted in *Pharmaceutical Journal*:

Most drugs are small organic molecules. The only differences between one drug and another are the number and type of functional groups present, and the connectivity between these groups. With this in mind, it should therefore not be surprising that drugs undergo chemical reactions in much the same way as other organic molecules under set conditions.[3]

These chemical reactions can affect API levels, introduce impurities, and compromise both the therapeutic value and safety of the medication. Spectrophotometric determination of potency and contaminants in response to forced, accelerated, and real-time aging gives researchers a simple, accurate, and reliable method of **monitoring vital drug stability indicators** at any stage of product development or manufacturing, whether a drug is in initial testing phases or in commercial production. When used early in the development process, these tests can provide critical guidance regarding the potential commercial viability of particular medications, giving researchers they need to make prudent decisions regarding where to invest time and resources.

Accelerated and forced aging allows researchers to rapidly simulate the effects of environmental stressors to observe drug behavior over time.
Image Source: Flickr user Be.Futureproof

HunterLab Quality

HunterLab has been a pioneer in spectral analysis for over 60 years.Today, we offer a comprehensive range of UV-Vis spectrophotometers ideally suited to meet the needs of the pharmaceutical industry. With extraordinary accuracy, sophisticated optical technologies, and user-friendly designs, our instruments offer unprecedented insight into drug quality and stability at all stages of the development and throughout manufacturing. **Contact us**to learn more about our renowned spectrophotometers, customizable software packages, and world-class customer support services.

1. "Testing Drug Stability for Long-Term Storage," October 5, 2012,

   http://www.dddmag.com/articles/2012/10/testing-drug-stability-long-term-storage

2. "Factors Affecting the Stability of Drugs and Drug Metabolites in Biological Matrices," April

   2009, http://www.ncbi.nlm.nih.gov/pubmed/21083197

3. "Understanding the Chemical Basis of Drug Stability and Degradation," October 8, 2010, http://www.pharmaceutical-journal.com/opinion/comment/understanding-the-

   chemical-basis-of-drug-stability-and-degradation/11029512.article