Dietary Supplement Quality: The Meaning of the USP Verified Mark

Approximately 150 million Americans use dietary supplements annually. With the availability of many different brands and types of dietary supplements in stores and pharmacies, product selection can be daunting. Pharmacists are often the health care professionals patients rely on for information on dietary supplements.

Recent press regarding quality and safety issues in the dietary supplement industry may lead more consumers to ask questions about quality issues related to dietary supplements, making counseling consumers more challenging. 

Although pharmacists may already be familiar with the United States Pharmacopeial Convention (USP), additional knowledge of USP standards in the context of dietary supplements may help pharmacists be more confident in making recommendations regarding these products.

FDA Regulations and USP
In 2007, the FDA issued its final guidance on Current Good Manufacturing Practices (cGMPs) for dietary supplements. Under the cGMPs, manufacturers are required to establish their own quality standards for manufacturing processes, packaging, storage, and ingredient testing, and must properly document that these standards are being met. For example, the cGMPs stipulate that manufacturers must take all necessary precautions to prevent contamination. Manufacturers are also required to verify that their laboratory examination and testing methodologies are appropriate.

The USP Verified Mark
USP is often associated with pharmaceutical products and ingredients. There may be less awareness among pharmacists and consumers with regard to USP’s quality standards for dietary supplements and the robustness of the USP Dietary Supplement Verification Program (“DSVP”) that stands behind those standards. Dietary supplement products are awarded use of the “USP Verified” Mark on their label to indicate that, in addition to meeting FDA requirements, they have met USP’s own product-specific standards.

Before a dietary supplement is accepted into the DSVP, the USP staff, in consultation with the appropriate USP expert committee, evaluates the supplement to ensure that it does not contain any ingredients with known safety concerns. This initial screening helps to ensure that supplements with known safety concerns do not become part of the DSVP. To verify the quality of dietary supplements, USP’s DSVP staff conducts extensive on-site facility GMP audits of manufacturing operations, reviews product documentation, and tests product samples.
Unlike the FDA cGMP regulations, USP sets quality standards that are product specific. USP creates dietary supplement monographs that outline appropriate tests and analytical test methods to be used (eg, chromatography). USP dietary supplement monographs contain detailed specifications for identification, potency, and purity, and include information regarding compounds known to be harmful (eg, alkaloids or terpenes). Testing is designed to verify that dietary supplements contain the ingredients listed on the label, with the correct potency and amount of dietary ingredient, and that harmful levels of contaminants, such as heavy metals, pesticides, bacteria, and molds, are not present. The DSVP provides additional safeguards for known issues with a given dietary supplement product. For instance, the supplement ginkgo biloba often contains ginkgolic acids that are known for their potential to cause allergic reactions, as these acids are structurally similar to urushiol—the sensitizing oil present in poison ivy leaves. The USP monograph for ginkgo biloba sets stringent, product-specific requirements for levels of contaminants. Good product-specific manufacturing practices were followed.

A quality-conscious, independent scientific authority has tested the dietary supplement.

The DSVP staff for disintegration or dissolution to help ensure that the product will break down in the body, which is necessary for proper absorption.

The DSVP program includes annual on-site GMP audits conducted by USP scientists that check for continued compliance with both the FDA’s cGMPs and the USP’s product-specific GMPs. Finally, all dietary supplements awarded the USP Verified Mark are subject to annual post market surveillance testing.

**Role of the Pharmacist**

Pharmacists play an important role in helping consumers select dietary supplements manufactured by reputable companies. There are more than 70 USP-verified dietary supplement formulas, some of which are only available online. Nature Made brand vitamins, commonly available in stores, account for 47 of the USP-verified formulas.

When consumers ask for guidance on choosing a trustworthy brand, pharmacists can feel more confident in recommending products that have the USP Verified Mark because only these products are assured to meet the USP’s stringent quality standards.

Visit http://uspgo.to/ds-presentation for more information on the Dietary Supplement Verification Program.

**References**