USP Dietary Supplement Verification

The USP Verified Mark has appeared on more than 750 million labels!

USP is a scientific nonprofit organization that sets U.S. federally recognized standards for medicines and dietary supplements. USP has almost 200 years of experience supporting the quality of the U.S. drug supply. We also help ensure the quality of dietary supplement products by offering third-party verification services. These services not only help manufacturers produce quality products but also enhance their competitive position and brand recognition in the marketplace.

USP dietary supplement verification services include

- An on-site manufacturing facility audit for compliance with the U.S. Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMPs) (21 CFR Part 111) and *USP* General Chapter ‹2750 › *Manufacturing Practices for Dietary Supplements*
- A thorough review of manufacturing and quality control product documentation
- Comprehensive laboratory testing against applicable dietary supplement standards found in the *United States Pharmacopeia* and the *National Formulary (USP–NF)*
- Annual testing of products randomly sampled at retail stores to confirm that the USP-verified product continues to meet USP's strict standards

FOR MORE INFORMATION

About **USP Dietary Supplement Verification** or products that carry the **USP Verified Mark**, contact John Atwater at **+1-301-816-8529**, email **jba@usp.org** or visit **www.usp.org/dsvp**.

What the USP verified mark means

Because of their familiarity with USP's role in medicine, many doctors and pharmacists rely on the USP Verified Mark to provide the same assurance of consistency, quality and purity necessary to protect their patients who take dietary supplements. USP awards the USP Verified Mark only after rigorous reviews and testing of product samples.

Periodic testing of products on the market ensures that a verified product continues to meet USP's strict quality standards for verification. When seen on a dietary supplement label, the USP Verified Mark indicates the following:

- Ingredients listed on the label are present in the declared potency and amounts.
- The supplement does not contain harmful levels of specified contaminants.
- The supplement will break down and release ingredients into the body within a specified amount of time.
- The supplement has been made according to FDA cGMPs.

Products that meet USP's stringent verification criteria can display the USP Verified Mark on product labels, packaging and promotional materials—making it easy for healthcare practitioners, consumers and retailers to identify quality products on store shelves.

What to Expect When Participating in the Program:

1. **Product Appropriate for Inclusion:**
   Products need to contain ingredients that have an acceptable regulatory status in the U.S. (e.g., Generally Recognized as Safe (GRAS), self-affirmed GRAS or "grandfathered" ingredients). Participants need to provide product information including product labels and specifications with validated test methods.

2. **Audit of Manufacturing Sites for GMP Compliance:**
   USP verification program audits cover not only FDA 21 CFR Part 111 GMP requirements, but also *USP* ‹2750› GMP requirements for recall procedures, product shelf-life stability studies, product performance tests, properly characterized reference standards and validated test methods for release testing of all ingredients and finished products. USP conducts a six-quality-systems audit covering quality management, facilities and equipment, materials, production, packaging and labeling, and laboratory controls.

3. **Review of Quality Control and Manufacturing Product Documentation:**
   USP reviews manufacturing and quality control documentation to verify that manufacturing processes have clear instructions and in-process controls for critical steps, and that components, packaging, labels and finished products have been properly tested and released by the quality control group. All excipients, dietary ingredients and finished products need to conform to applicable compendial monograph standards.

4. **Laboratory Testing of Product Samples:**
   USP conducts full laboratory testing of product samples for identification, potency, limits on contaminants and performance characteristics to verify conformance to product specifications and applicable USP quality standards.

5. **Review of Conformance with Mark Usage Guidelines:**
   After the manufacturing facility has passed the GMP audit and the products have successfully undergone documentation review and testing, the product labels can bear the USP Verified Mark. USP reviews intended use of the Mark on labels and marketing materials to ensure the Mark is being properly represented.

6. **Continuous Surveillance Monitoring:**
   After awarding the Mark, USP continues to monitor the quality of verified products annually by conducting GMP facility audits, product documentation review and testing. USP reviews manufacturing changes that impact product quality. USP conducts product review and testing on USP verified product samples pulled randomly from retail store shelves to continually verify that what is on the label is in the bottle and that the product meets quality, potency and purity requirements.