USP Verification Services for Ingredients

USP offers rigorous third-party verification services to help companies achieve quality management for ingredients used in the manufacture of finished drug products, dietary supplements and food products. Companies whose ingredients meet USP's comprehensive and stringent verification requirements, as noted below, are awarded a Certificate of Standards Compliance and use of the appropriate USP Verified Mark. The Mark can be used on the bulk label of each container of USP-verified ingredients, on the certificate of analysis and on other valuable marketing collateral.

Service	USP VERIFIED DIETARY INGREDIENT®	USP VERIFIED EXCIPIENT™	USP VERIFIED PHARMACEUTICAL INGREDIENT®
Verification Component	**Manufacturing Facility Audit** Demonstrates compliance with applicable Good Manufacturing Practice (GMP) requirements		
	Review of Quality Control and Manufacturing Product Documentation Helps ensure ingredient consistency from batch to batch		
	Laboratory Testing of Ingredient Samples Verifies conformance to appropriate specifications for identity, strength, purity and quality; meets acceptable limits for impurities and contaminants		
	Ongoing Change Monitoring and Surveillance Annual risk-based audits and tests of randomly selected lots to confirm that a USP-verified ingredient continues to meet program requirements		

What's the Value for Your Company?

- **Engage** in supplier qualification, potentially reducing audits from customer
- **Reduce the risk** of inconsistent and substandard ingredient quality
- **Differentiate your ingredient** and help maintain your sales edge in an increasingly competitive global market
- **Strengthen confidence** that GMP and product quality standards have been met

LEARN MORE

For more information on dietary ingredient verification, excipient verification and pharmaceutical ingredient verification, visit **www.usp.org/ivp**. To discuss participation, contact **uspverified@usp.org**.

Why USP?

- **Independent verification of quality**—Third-party scientific verification that is comprehensive and unbiased
- **Worldwide recognition**—USP standards are legally recognized in the U.S. and elsewhere, and are used in more than 140 countries. USP has laboratories in Brazil, China, India and the United States.
- **Experience**—Nearly 200 years of experience setting quality standards and more than 25 years helping international manufacturers and regulators understand and apply GMP principles to achieve regulatory compliance

Our goal is to ensure our service can add value in offering the proper guidance to provide quality reassurance to our customers. Our new program will verify that plans are in place to address the following FDA Food Safety Modernization Act (FSMA) requirements:

GMP Requirements

- Includes GMP requirements for food ingredients including those focused on sanitation and allergen cross-contamination reduction controls, and natural or unavoidable defect action levels
- Includes GMP requirements in *USP* General Chapter ‹2750› *Manufacturing Practices for Dietary Supplements* that are applicable to dietary ingredients
- Also, includes USP GMP requirements focused on dietary ingredients manufactured by chemical synthesis, extraction, cell culture fermentation, recovery from natural sources or any combination of these processes

Hazard Analysis and Risk-Based Preventative Controls Plan

- Includes new FSMA requirements that apply to domestic and foreign facilities, including the need to adopt a food safety plan, to perform a hazard analysis and to institute and monitor preventive controls for the mitigation of identified hazards
- Includes requirements to institute risk-based environmental monitoring, product testing and a supply-chain program as appropriate to the food, the facility and the nature of preventive controls, as well as a requirement to institute controls to help prevent hazards associated with economically motivated adulteration

FSMA Supply-Chain Controls

- Includes risk-based supply-chain assessment for raw materials and ingredients, review of sanitary transportation practices for prevention of raw material/ingredient adulteration and science-based mitigation strategies to protect against the intentional adulteration of food at vulnerable points in the supply chain

Foreign Supplier Verification Program

- The USP Ingredient Verification Program for dietary ingredients helps importers of dietary ingredients meet foreign supplier verification program to facilitate entry of imports into the United States.