

## Heavy Metal Testing for Dietary Supplements

by Anthony DeStefano, Ph.D., and Kakhkashan Zaidi, Ph.D.

Heavy metal contamination in some botanical and non-botanical dietary supplements and their ingredients is a well-recognized problem. Botanical dietary supplements can vary widely in heavy metal content as a function of the part of the plant used and where it was grown. The ever-increasing reliance on imported pharmaceutical excipients, food ingredients and dietary supplements can only lead to the problem becoming more widespread. There are currently no uniform federal standards for permissible levels of metals in dietary supplements, and cGMPs (current good manufacturing practices) for dietary supplements put the onus on manufacturers to set the standards, including the acceptance criteria for precision and accuracy of the measurements.

The U.S. Pharmacopeial (USP) Convention provides monographs for active pharmaceutical ingredients, drug products, excipients, food ingredients and an increasingly large number of dietary supplements. As a non-profit public health resource, USP has an ongoing interest in assuring the levels of any impurities materials are correctly identified, well-controlled and properly measured. To help manufacturers, USP is developing a Dietary Supplements Compendium that will be available early in 2009. This reference publication will be dedicated entirely to dietary supplements and will

include quality specifications that test for identity, purity and content, as well as methods of analysis and acceptance criteria. The goal is to help manufacturers navigate the regulatory framework as well as provide USP verification programs for dietary supplements and reference chromatograms.

Heavy metals tests have been available in the USP—Natural Formulary (USP-NF) for many years. These tests include the general heavy metals screening tests contained in General Chapter <231>, Heavy Metals, as well as other general chapters with specific tests for individual elements of concern such as aluminum, arsenic, iron, lead, mercury and selenium. The screening tests in <231> are non-element-specific limit tests, which are only applicable for a relatively small group of elements. The element-specific tests are also chemical tests, some of which require skilled analysts to perform properly.

With the increasing number of monographs devoted to dietary supplements, there is a need to broaden the number of elements for which limits are established, and to improve the quality of the measurements. Current sample preparation and instrumental technology (e.g., closed-vessel microwave digestion followed by atomic absorption spectroscopy and inductively-coupled

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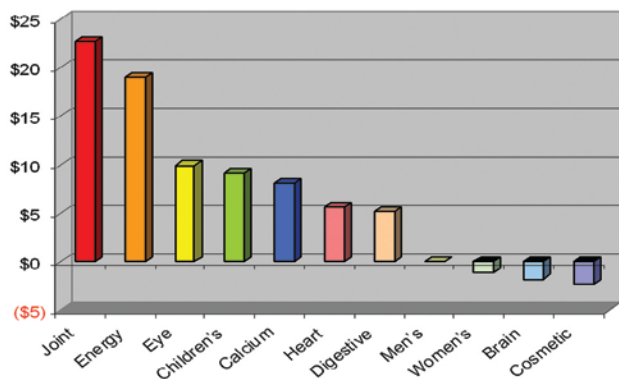
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Note: Figures are based on IRI sales tracking through U.S. supermarkets, drugstores and mass merchandisers other than Walmart. Source: Information Resources, Inc. InfoScan Review; compiled by Packaged Facts. This material is used with permission. Report: Nutritional Supplements in the U.S., Third Edition


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plasma spectroscopy with various modes of detection) permit the quantification of a broad range of elements at low levels with excellent precision and accuracy. Given the widespread availability of this technology, it is important to look at heavy metals testing in a holistic way and begin the process of updating heavy metals testing to be element-specific and performance-based (defined by its analytical requirements rather than by a particular methodology).

The USP revision process began with a Stimulus to the Revision Process article, which appeared online (USP.org) in May 2008 and in print in the *Pharmaceutical Forum* 34(5) in September 2008. The Stimulus article listed approximately 30 elements of interest to USP and discussed potential testing procedures and limits. The article expanded on the concepts and the number of elements discussed in a recently published EDQM Guidance on limits for catalysts in pharmaceuticals.

To better establish limits for these metals, USP also asked the Institute of Medicine to convene a workshop to discuss the toxicology and measurement science associated with these metals. This important meeting took place in Washington, D.C. on Aug. 26 to 27, 2008; and further discussions took place during USP's Annual Scientific Meeting in Kansas City, Mo., in September. The proceedings from these workshops will be used to develop a draft chapter to be made available for public comment. USP intends the outcome of this effort to be a widely applicable, scientifically sound test with toxicologically realistic limits for the various metals. Public comment at each stage of the process is encouraged. □

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### Heavy Metals & Ayurveda

Researchers from the Boston Medical Center recently published a study in *JAMA* (2008;300(8):915-23) that reported one-fifth of Ayurvedic remedies purchased over the Internet contained detectable levels of toxic heavy metals; the same team reported similar findings in 2004 concerning Ayurvedic products purchased in Boston-area retail stores.

India's Department of Ayush and the Ayurvedic Drug Manufacturer's Association (ADMA) both responded to the *JAMA* findings, criticizing the study as seriously flawed and suggesting the authors have a strong bias against Ayurvedic medicines and were maligning the reputation of the centuries-old system of medicine.

In fact, India's Department of AYUSH enforced mandatory testing for heavy metals in Ayurveda, Siddha and Unani herbal products being exported from India, as testing is a part of Good Manufacturing Practices (GMPs) finalized by India in 2003.

This topic, and other hot information on the Indian market and its products, will be addressed during SupplySide West in a two-part education session on India, set for Oct. 23 and 24. Details are available online ([SupplySideShow.com](http://SupplySideShow.com)) or in the Show Guide on-site in Las Vegas.