General Chapter <231> Heavy Metals and Affected Monographs and General Chapters

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Expert Committee: General Chapters—Chemical Analysis

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, the General Chapters—Chemical Analysis Expert Committee, has revised the omission date of General Chapter <231> Heavy Metals, concurrent with the Revision Bulletin for General Notices Section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements approved by Council of Experts—Executive Committee. Congruently, all references to General Chapter <231> in *USP–NF* monographs and general chapters are also being revised to align with the new omission date of this General Chapter.

A list of the referenced monographs and General Chapters can be found here.

The intent of this revision is to delay in omission of General Chapter <231> Heavy Metals until January 1, 2018 to align with the applicability of General Chapters <232> Elemental Impurities–Limits and <2232> Elemental Contaminants in Dietary Supplements. These changes are being made to more closely align the implementation date of USP's Elemental Impurities standards with the ICH Q3D Guideline for Elemental Impurities.

The General Chapter <231> Revision Bulletin and the associated reference changes to the monograph listed below supersedes the currently official monograph, but will not be implemented until January 1, 2018. The Revision Bulletin and the associated reference changes will be incorporated in the *USP 39–NF 34*.

Please also see the Compendial Notice: New Revision Markup for Reference Changes in *USP–NF* for details on the revision markup used to identify the reference updates.

Should you have any questions or comments, please contact Kahkashan Zaidi, Ph.D., Principal Scientific Liaison (301-816-8269 or kxz@usp.org).

- Download the General Chapter <231> Heavy Metals Revision Bulletin