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

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Official Date: 01–Apr–2015 (Implementation Date: 01–Jan–2018)

Expert Committee: General Chapters—Chemical Analysis

In accordance with 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.

Beginning with *USP 38–NF 33*, for certain monographs and general chapters that previously referenced General Chapter <231>, the reference to <231>, or “Heavy Metals,” will only be indicated by (Official 01-Jan-2018) and the actual reference to <231> will not be present in future revisions of these standards. In these cases the reference to General Chapter <231> will still be considered official until January 1, 2018 (when the omission of General Chapter <231> becomes official), even though this reference does not appear. A list of the monographs that USP has identified that will be missing the “to be deleted” <231> requirement can be found [here](#).

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](#)

*The notice was updated on April 29, 2015 to remove the reference to section 7.05(c) of the 2010-2015 Rules and Procedures of the Council of Experts in the opening sentence, because this section applies to Notices of Intent to Revise.

** The notice was updated on May 12, 2015 to include information on the monographs that will be missing the reference to General Chapter <231> beginning in *USP 38–NF 33*, even though this requirement will still be applicable to these monographs until January 1, 2018. This information was originally included in the Notice of Intent to Revise for this revision that was posted on July 26, 2014. The associated list of monographs and General Chapters that are missing the reference to <231> was also updated.