



## USP Revision and Implementation Plan for the Elemental Impurities General Chapters <232> *Elemental Impurities—Limits*, <233> *Elemental Impurities—Procedures*, and <2232> *Elemental Impurities in Dietary Supplements*

December 27, 2013

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### Background

#### General Chapters <232> *Elemental Impurities—Limits*, <233> *Elemental Impurities—Procedures*

On September 23, 2013, the Elemental Impurities Expert Panel met to review the Step 2 limits of the ICH Q3D Elemental Impurities Working Group, which were released in June 2013. At its meeting the Expert Panel recommended revisions to General Chapter <232> *Elemental Impurities—Limits* to partially align with the ICH Q3D limits. In addition, the Expert Panel recommended other minor editorial changes to both General Chapter <232> and General Chapter <233> *Elemental Impurities—Procedures*. On October 16-17, 2013 the General Chapters—Chemical Analysis Expert Committee met and endorsed the recommendations of the Expert Panel. The revisions will be posted to USP's web site to provide an extended opportunity for public comment on the proposed changes in advance of its publication in *Pharmacopeial Forum* 40(2).

#### General Chapter <2232> *Elemental Contaminants in Dietary Supplements*

General Chapter <2232> was published February 1, 2013 in the *First Supplement to USP 36-NF 31* and became official on August 1, 2013.

#### General Notices section 5.60.30 *Elemental Impurities in USP Drug Products and Dietary Supplements*

In December 2013, the Council of Experts approved General Notices section 5.60.30 *Elemental Impurities in USP Drug Products and Dietary Supplements*, which includes specific timing for the applicability of General Chapters <232> *Elemental Impurities—Limits* and <2232> *Elemental Contaminants in Dietary Supplements* to drug products and dietary supplements recognized in the *USP–NF*.

### Revision Timeline

- **December 27, 2013:** USP posts the final version of General Notices section 5.60.30, which includes the date of applicability of <232> and <2232>. USP also pre-publishes on the USP Elemental Impurities Key Issues web page the proposed revisions to <232> and <233>.
- **March 1, 2014:** USP publishes the proposed revisions to <232> and <233> in *PF* 40(2) [March-April 2014] for public comment. Comments will be accepted only on the proposed revisions to the general chapters.
- **May 31, 2014:** The 90-day comment period ends (comment period is from March 1, 2014 through May 31, 2014).
- **May 2014:** The General Chapters—Chemical Analysis Expert Committee ballots on the removal of General Chapter <231> *Heavy Metals*. Note that the removal of <231> was previously proposed in *PF* 39(1) [January-February 2013] and will specify an

- official date that aligns with the applicability of General Chapters <232> and <2232>, which is specified in General Notices section 5.60.30 as December 1, 2015.
- **June 2014:** The Expert Panel considers comments received on the proposed revisions and also reviews ICH Q3D Step 4 limits, which are expected in June 2014. The revised General Notices appears in the *Second Supplement to USP 37-NF 32* with an official date of December 1, 2015.
  - **July-August 2014:** The Expert Panel meets to make recommendations regarding any final revisions to revised General Chapters <232> and <233>.
  - **September 2014:** General Chapters—Chemical Analysis Expert Committee meets to review Elemental Impurities Expert Panel recommendations and consider final revisions to revised General Chapters <232> and <233>.
  - **October 2014:** The General Chapters—Chemical Analysis Expert Committee ballots on the revised General Chapters <232> and <233>.
  - **October 2014:** USP pre-posts the approved revised General Chapters <232> and <233>, the Commentary, and a notice about the removal of General Chapter <231> on the USP Elemental Impurities Key Issues web page.
  - **November 2014:** All references to <231> in individual *USP 38-NF 33* monographs are removed in with official dates of December 1, 2015, which align with the applicability of <232> and <233> via General Notices 5.60.30.
  - **February 2015:** The approved revised General Chapters <232> and <233> are published in the *First Supplement to USP 38-NF 33*, which publishes in February 2015 and becomes official August 1, 2015.
  - **August 1, 2015:** The *First Supplement to USP 38-NF 33* becomes official, including revised General Chapters <232> and <233>
  - **December 1, 2015:** General Notices section 5.60.30 becomes official, making <232> and <2232> applicable to drug product monographs. The *Second Supplement* becomes official, including the omission of General Chapter <231>.