General Notices Section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements

Type of Posting: Revision Bulletin

Posting Date: 27–Mar–2015

Official Date: 01–Apr–2015

Expert Committee: Council of Experts Executive Committee

Reason for Revision: Compliance

In accordance with section 7.02 of the 2010–2015 Rules and Procedures of the Council of Experts, the Council of Experts Executive Committee (CoE EC) has revised General Notices Section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements as a Revision Bulletin published on March 27, 2015. The revised text will become official April 1, 2015.

The intent of this revision is to establish an implementation date of January 1, 2018 for General Chapters <232> Elemental Impurities–Limits and <2232> Elemental Contaminants in Dietary Supplements. This date more closely aligns the implementation date of Elemental Impurities standards with that of the ICH Q3D Guideline for Elemental Impurities.

Following the December 2014 release of the ICH Q3D Guideline for Elemental Impurities and based on dialogue with representatives of industry and the Food and Drug Administration, the CoE EC has revised section 5.60.30 as follows:

Specify the timing of the applicability of General Chapters <232> and <2232> for January 1, 2018 to align more closely with the implementation date of the ICH Q3D Guideline for existing products

- Note the delay in omission of General Chapter <231> Heavy Metals until January 1, 2018 to align with the applicability of <232>
- Allow early adoption of the General Chapters <232> and <2232> in the interim to enable users to determine whether to use the existing <231> or the new <232>/<2232> approaches

USP has posted a separate Revision Bulletin to delay the omission of General Chapter <231> Heavy Metals and its references in monographs.

Should you have any questions, please contact Mario Sindaco, Director, Compendial Affairs and Executive Secretariat, Council of Experts (301-816-8246 or mys@usp.org).

- Download the General Notices: Section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements Revision Bulletin