

USP Open Forum | Excipients

Elemental Impurities Update

Kahkashan Zaidi, Ph.D.
Principal Scientific Liaison



Objectives

This presentation will highlight:

- ▶ The current status of elemental impurities chapters <232> and <233>.
- ▶ USP EI sub-committee's efforts regarding element-specific chapters.

Features of <232>

- ▶ Implemented on January 1, 2018
- ▶ Applies to drug products:
 - Options to test components and contributions from processing equipment, etc. OR test drug product when testing is required
- ▶ **Risk-based approach**
 - Generally not required to test everything for all potential elements
 - **Develop a risk assessment**

<233> Elemental Impurities --Procedures

- ▶ <233> -- official since Jan 2018
- ▶ Harmonization through PDG
 - Proposal in PF 46(3)
 - Comment period ended on July 31, 2020

USP Element-Specific Chapters and Elemental Impurities

- ▶ USP has several chapters that address specific elements
 - Aluminum, Arsenic, Selenium, Mercury, Lead---
- ▶ With the exception of Al; As, Se, Hg and Pb are all elements that are potentially needed for risk assessment for USP <232>
- ▶ How to reconcile method of analysis from <233> (used with <232>) and element-specific chapters?

- ▶ Revision to following element-specific chapters to permit testing procedure used in USP <233>/ICP based Procedures in PF47(1)
 - <206> Aluminum
 - <211> Arsenic
 - <241> Iron
 - <251> Lead
 - <261> Mercury
 - <291> Selenium
- Comment Period ending on March 31, 2021
- Can still use “old” testing procedures, per the individual chapters

Small Molecules Approach

- ▶ Removing all tests for elements that are part of USP <232>/ICH Q3D elemental impurities list from drug substance monographs
- ▶ Number of revisions have appeared in PF

PF 43(6)	1	Officail in USP42 1S
PF 46(4)	10	8 moved to ballot for USP2021 Issue 3
PF 46(5)	12	
PF 46(6)	5	
PF 47(1)	3	
Total	31	

Thank You



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Kahkashan Zaidi, Ph.D. | Principal Scientific Liaison
Phone: (301) 816-8269 | Email: kxz@usp.org | www.usp.org

