独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

General Chapter Elemental Impurities (G-07) Harmonised By The Pharmacopoeial Discussion Group

The new harmonised general chapter "Elemental Impurities (G-07)" was signed-off by the Pharmacopoeial Discussion Group (PDG) on 19 June 2024. The PDG brings together the European Pharmacopoeia (Ph. Eur.), Indian Pharmacopoeia Commission (IPC), Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP).

The implementation of this harmonised chapter along with the application of the concepts of the ICH Q3D Guideline, which includes appropriate limits for specific elemental impurities together with a process for their assessment and control, promote the development of individual monographs with aligned requirements for elemental impurities among the regions of the PDG pharmacopoeias. The PDG started working on a harmonised general chapter for application in their respective regions, with USP as coordinating pharmacopeia in June 2014.

During the development of the harmonised text, the participating pharmacopoeias focused on including the updated requirements described in the ICH Q3D Guideline and also achieved harmonisation on acceptable approaches for analytical procedures, specifically on the following topics:

- Sample preparation
- Examples of applicable procedures and detection techniques
- Requirements for procedure validation

The corresponding regional texts for the harmonised general chapter "Elemental Impurities" are scheduled for publication in July 2025 (Ph. Eur.), December 2025 (USP), April 2026 (JP) and July 2026 (IPC).

This sign-off represents an important milestone in itself, but it also constitutes a more global achievement as the PDG has now successfully harmonised all the general chapters on its work programme (31) in addition to 48 of the 62 excipient monographs listed. The current work programme, including all ongoing items, is available on the website (General Chapters [link], Excipients [link]).

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