

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The Pharmacopeial Discussion Group Releases Major Revision to General Chapter Q-09: Particulate Contamination

The revised harmonised general chapter “Particulate Contamination (Q-09)” was signed-off by the Pharmacopeial Discussion Group (PDG) on 2 May 2025. The PDG brings together the European Pharmacopoeia (Ph. Eur.), the Indian Pharmacopoeia Commission (IPC), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP).

The revision of Q-09 represents a significant step forward in standardised testing procedures for sub-visible particulate matter in all injectable products applied in the PDG regions. This update makes the process more robust and adaptable to different product types, including biologicals. Major changes include:

- Definition clarification
- Guidance on sample preparation, especially for formulations with a volume of 25 mL or less
- Method 1 (light obscuration particle count test) updates
- Method 2 (microscopic particle count test) updates

These revisions ensure clear, comprehensive standards aligned with current scientific and regulatory expectations, ultimately contributing to improved drug development and public health. The well-established acceptance criteria have been kept from the previous version of the text. The full sign-off text can be found on the website ([link](#)). The corresponding regional texts for the harmonised general chapter on Particulate Contamination are scheduled for publication in April 2026 (JP general test <6.07>), July 2026 (Ph. Eur. general chapter 2.9.19), and July 2025 (USP text <788> with <787> to be omitted in the future). The IPC as newest member will sign and implement the text at a later stage according to its implementation plan for all PDG harmonised texts.

The PDG has 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](#), [Excipients](#)).

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