



Commentary

USP-NF January 2026

January 30, 2026

In accordance with USP's *Rules and Procedures of the 2025-2030 Council of Experts (CoE Rules)*, and except as provided in Section 9.02 *Accelerated Revision Processes*, USP publishes proposed revisions to the *United States Pharmacopeia and the National Formulary (USP–NF)* for public review and comment in the *Pharmacopeial Forum (PF)*, USP's free bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee (EC) deems appropriate, the proposal may advance to official status or be re-published in *PF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status, a summary of comments received and the appropriate Expert Committee's responses, as well as Expert Committee-initiated changes, are published in the Proposal Status/Commentary section of USP.NF.com at the time the official revision is published.

The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference or conflict between the contents of the *Commentary* and the official text, the official text prevails.

For further information, contact:
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United States Pharmacopeia
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Comments were received for the following when they were proposed in Pharmacopeial Forum:

Monographs

AZEOTROPIC ISOPROPYL ALCOHOL
ISOPROPYL ALCOHOL

Monograph

Monograph: AZEOTROPIC ISOPROPYL ALCOHOL (43160)
Expert Committee: Simple Excipients
No. of Commenters: 1

Impurities – Limit of Volatile Impurities

Comment Summary #1: The commenter proposed replacing Standard Solutions A and B in the “*Impurities – Limit of Volatile Impurities*” test with the USP 2-Propanol System Suitability RS outlined in PF 51(5). The commenter made this suggestion because they believe the change will reduce costs and stakeholder burden, streamline workflows, and minimize environmental impact by eliminating solvent use and waste associated with preparing the current standard solutions. The commenter also suggested formulas for calculations to accommodate the use of USP 2-Propanol System Suitability RS in place of Standard Solutions A and B.

Response: Comment not incorporated. While the suggestion to replace Standard Solutions A and B with the new USP 2-Propanol System Suitability RS may be considered in the future, it cannot be adopted because at this time because Standard Solutions A and B are prepared in the Sample, whereas the 2-Propanol System Suitability solution is prepared using a different lot of Isopropyl Alcohol as the solvent, which has different impurity levels. Therefore, the current monograph’s calculation formulas cannot be directly applied and will require adjustment. Furthermore, the new USP 2-Propanol System Suitability RS is currently intended for qualitative use only, not quantitative use.

Monograph: ISOPROPYL ALCOHOL (43140)
Expert Committee: Simple Excipients
No. of Commenters: 1

Impurities - Limit of Volatile Impurities

Comment Summary #1: The commenter proposed replacing Standard Solutions A and B in the “*Impurities – Limit of Volatile Impurities*” test with the new USP 2-Propanol System Suitability RS outlined in PF 51(5). The commenter made this suggestion because they believe the change will reduce costs and stakeholder burden, streamline workflows, and minimize environmental impact by eliminating solvent use and waste associated with preparing the current standard

solutions. The commenter also suggested formulas for calculations to accommodate the use of USP 2-Propanol System Suitability RS in place of Standard Solutions A and B.

Response: Comment not incorporated. While the suggestion to replace Standard Solutions A and B with the new USP 2-Propanol System Suitability RS may be considered in the future, it cannot be adopted at this time because Standard Solutions A and B are prepared in the Sample, whereas the 2-Propanol System Suitability solution is prepared using a different lot of Isopropyl Alcohol as the solvent, which has different impurity levels. Therefore, the current monograph's calculation formulas cannot be directly applied and will require adjustment. Furthermore, the new USP 2-Propanol System Suitability RS is currently intended for qualitative use only, not quantitative use.