



Commentary

Interim Revision Announcements

January 27, 2023

In accordance with USP's *Rules and Procedures of the Council of Experts ("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.

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Monographs

Isotretinoin Capsules

Monograph/Section(s): Isotretinoin Capsules/Performance Tests: Dissolution Test 6

Expert Committee: Small Molecules 3

No. of Commenters: 0

Expert Committee-initiated Change: Change the “(see Table 1)” to “(see Table 2)” in the definition of dilution factor D in Dissolution Test 6 to accommodate the addition of Table 1 in the Assay Procedure 2.