



Commentary

Interim Revision Announcements published in February 2024

February 23, 2024

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 USPNF.com once 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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Monograph/Section(s): Sitagliptin Tablets/Organic Impurities

Expert Committee: Small Molecules 3

No. of Commenters: 2

Comment Summary: The commenter indicated concerns with the corrected elution order of the two Sitagliptin styrylacetyl analog and Sitagliptin phenylcrotonyl analog impurities.

Response: Comment not incorporated. The change to elution order was based on monograph sponsor data.