



Commentary

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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 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 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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Comments were received for the following when they were proposed in Pharmacopeial Forum:

Monographs

Orlistat

No comments were received for the following proposals:

Monographs

Ipratropium Bromide Inhalation Solution

Orlistat Capsule

Monograph/Section: Orlistat/Organic Impurities
Expert of Committee: Small Molecules 2
No. of Commenters: 1

Comment Summary #1: The commenter recommended revising the limit for any individual unspecified impurity from NMT 0.1% to NMT 0.10% to be consistent with ICH Q3A guidelines.

Response: Comment not incorporated. The comment is outside of the scope of the revision. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.