



Commentary

Interim Revision Announcements

March 25, 2022

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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United States Pharmacopeia
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Rockville, MD 20852-1790 USA

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

[Paclitaxel](#)

[Tetracycline](#)

[Tetracycline Hydrochloride](#)

[Tetracycline Hydrochloride Capsules](#)

No comments were received from the following proposals:

Carbidopa and Levodopa Tablets

Monograph/Section(s): Paclitaxel/Organic Impurities

Expert Committee: Small Molecules 3

No. of Commenters: 1

Comment Summary #1: The commenter requested to introduce Relative Response Factor (RRF) to the acceptance criteria table of Test 3.

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.

Monograph/Section: Tetracycline/Organic Impurities

Expert Committee: Small Molecules 1

No. of Commenters: 1

Comment Summary #1: The commenter recommended removing the reporting threshold as it will vary based on product-specific factors.

Response: Comment not incorporated. Based on comments received on a proposed policy for reporting thresholds, USP determined that removal of reporting thresholds from monographs needs further stakeholder engagement. USP intends to do further stakeholder engagement.

Monograph/Section: Tetracycline Hydrochloride/Organic Impurities

Expert Committee: Small Molecules 1

No. of Commenters: 2

Comment Summary #1: The commenter recommended removing the reporting threshold as it will vary based on product-specific factors.

Response: Comment not incorporated. Based on comments received on a proposed policy for reporting thresholds, USP determined that removal of reporting thresholds from monographs needs further stakeholder engagement. USP intends to do further stakeholder engagement.

Comment Summary #2: The commenter indicated that increased impurity limit for 2-Acetyl analog was observed and requested evaluating the impact of the proposed method to the impurity limits.

Response: Comment not incorporated. The Expert Committee determined the proposed method is suitable to quantify the impurities accurately. USP has not received any information from any manufacturer to widen the acceptance criteria.

Monograph/Section: Tetracycline Hydrochloride Capsules/Organic Impurities

Expert Committee: Small Molecules 1

No. of Commenters: 1

Comment Summary #1: The commenter recommended removing the reporting threshold as it will vary based on product-specific factors.

Response: Comment not incorporated. Based on comments received on a proposed policy for reporting thresholds, USP determined that removal of reporting thresholds from monographs needs further stakeholder engagement. USP intends to do further stakeholder engagement.

Comment Summary #2: The commenter indicated their concern regarding practice of referencing certain impurities in drug product monographs with a footnote indicating that they are process impurities and not to be reported or included in the total degradation products and specifically recommended removal of the 2-Acetyl analog from the impurity table (Table 4).

Response: Comment not incorporated. The comment is outside the scope of the proposed revisions. The Expert Committee will consider future revisions to the monograph if necessary.