



Commentary

Interim Revision Announcements posted September 25, 2020

October 14, 2020

In accordance with USP's *Rules and Procedures of the Council of Experts* ("Rules"), and except as provided in Section 7.02 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 republished in *PF* for further notice and comment, in accordance with the *Rules*. In cases when proposals advance to official status without re-publication in *PF*, a summary of comments received and the appropriate Expert Committee's responses are published in the Proposal Status/Commentary page 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 between the contents of the *Commentary* and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary*, shall prevail.

For further information, contact:
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No Comments were received for the following:

Telmisartan and Amlodipine Tablets

Comments were received for the following when they were proposed in PF:

Monographs

Stearyl Alcohol

Cetyl Alcohol

Monographs

Monograph/Section: Stearyl Alcohol/Multiple Sections

Expert Committee: Complex Excipients

Comment Summary #1: Commenter recommended to remove the titrant (hydranal-composite 2) and solvent (hydranal-lipoSolver MH) details or add note as suggested titrant and solvent.

Response: Comment not incorporated. The Expert Committee retained the proposed procedure with the titrant (hydranal-composite 2) and solvent (hydranal-lipoSolver MH) details. The Expert Committee determined that the solvent composition recommendation from the commenter (mixture of chloroform and ethanol) could not be implemented by stakeholders in some regions due to limits on chloroform utilization. [Note: this comment response was updated on October 14, 2020 to include the recommended composition provided by the commenter]

Comment Summary #2: Commenter reported 1-pentadecanol, internal standard (IS), is one of the related alcohols in the Stearyl Alcohol *NF* raw material from animal sources.

Response: Comment partially incorporated. The Expert Committee responded by incorporating a Note to indicate the unsuitability of Assay and Organic impurity test-1 methods for stearyl alcohol derived from animal sources. Commenter is encouraged to assist with USP by submitting their method development and validation data.

Comment Summary #3: Commenter recommended removing internal standard from Table 3 Organic Impurity Test 1 as quantification is based on area normalization.

Response: Comment not incorporated. The Expert Committee responded that the internal standard was listed in Table 3 for peak identification purpose only. It's required to identify each related fatty alcohol peak in the Sample solution based on those in the Resolution solution.

Comment Summary #4: Commenter suggested another improvement of Organic Impurity Test 1 in these monographs by replacing test for Iodine Value.

Response: Comment not incorporated. The Expert Committee responded that these recommendations will be considered in the upcoming revisions to this monograph.

Monograph/Section: Cetyl Alcohol/ Impurity

Expert Committee: Complex Excipients

Comment Summary #1: Commenter suggested another improvement of Organic Impurity Test 1 in these monographs by replacing test for Iodine Value.

Response: Comment not incorporated. The Expert Committee responded that these recommendations will be considered in the upcoming revisions to this monograph.

