



Commentary

Interim Revision Announcements proposed in: *Pharmacopeial Forum* 40(2) [Mar.–Apr. 2014]

July 26, 2014

In accordance with USP's Rules and Procedures of the 2010-2015 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 republication in *PF*, a summary of comments received and the appropriate Expert Committee's responses are published in the Revisions and Commentary section of the USP Web site 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.

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

Monograph/Sections: Cefdinir Capsules/Assay
Expert Committee: Monographs—Small Molecules 1
No. of Commenters: 1

Comment Summary #1: The commenter requested correcting the Assay acceptance criteria to match the information in the *Definition*.

Response: Comment incorporated.

Monograph/Sections: Cefdinir for Oral Suspension/Labeling
Expert Committee: Monographs—Small Molecules 1
No. of Commenters: 1

Comment Summary #1: The commenter requested deleting the *Labeling* requirement because this information is available in *General Notices 10.40.10* and is not required in the individual monograph.

Response: Comment incorporated.

Monograph/Sections: Chlorhexidine Gluconate Solution / Organic Impurities
Expert Committee: Monographs—Small Molecules 3
No. of Commenters: 2

Comment Summary #1: The commenter indicated that the equilibration time specified in the proposal may not be sufficient, and requested to provide flexibility to the user.

Response: Comment incorporated. The equilibration time was removed from the gradient table and a note was added, "Return to original conditions, and equilibrate the system."

Comment Summary #2: The commenter indicated that the blank shows a peak at the retention time of the Chlorhexidine gluconate peak.

Response: Comment not incorporated. The issue was not observed during evaluation of the procedure and may be due to carry-over.

Comment Summary #3: The commenter requested to include the calculation equation.

Response: Comment not incorporated. This issue was addressed prior to publication of the proposal for public comment.

Monograph/Sections: Chlorhexidine Hydrochloride / Organic Impurities
Expert Committee: Monographs—Small Molecules 3
No. of Commenters: 2

Comment Summary #1: The commenter requested to revise Table 4 to read, "Any individual unspecified impurity" to be consistent with the other two drug substance monographs in the family.

Response: Comment incorporated.

Expert Committee initiated Change #1: The equilibration time was removed from the gradient table and a note was added "Return to original conditions, and equilibrate the system."

Monograph/Sections: Chlorhexidine Acetate / Organic Impurities
Expert Committee: Monographs—Small Molecules 3
No. of Commenters: 1

Expert Committee initiated Change #1: The equilibration time was removed from the gradient table and a note was added "Return to original conditions, and equilibrate the system."

No comments received for the following, when they were proposed in Pharmacopeial Forum:

Polysorbate 20