Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 39(1) [Jan.–Feb. 2014]**

May 30, 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.

For further information, contact:

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

Monograph/Section(s): Famciclovir/Multiple Sections
Expert Committee: Monographs—Small Molecules 1
No. of Commenters: 2
Comment Summary #1: The commenter recommended revising the impurity trivial name in the test for *Organic impurities* Procedure 2 from "Famciclovir 7, N^2-dimer" to "Famciclovir 8, N^2-dimer", to be consistent with the IUPAC chemical name.
Response: Comment incorporated.
Comment Summary #2: The commenter requested including sample solution stability information under *Assay*.
Response: Comment not incorporated. The proposal as written is consistent with the validation data.
Comment Summary #3: The commenter indicated that the Sample solution concentration of 30 mg/mL in the test for *Organic impurities* Procedure 3 may cause carryover peak in the subsequent run.
Response: Comment not incorporated. The test for *Organic impurities* Procedure 3 is a limit test for individual specified impurities and the carryover of the famciclovir peak is not relevant for the analysis.
Expert Committee initiated Change #1: The calculation in the test for *Famciclovir Related Compound E and Famciclovir Related Compound F* was revised to determine the result in ppm rather than as a percentage, to be consistent with the Acceptance criteria

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

High Frutctose Corn Syrup

Escitalopram Oxalate

Tamsulosin Hydrochloride Capsules