



Commentary

Interim Revision Announcements proposed in: *Pharmacopeial Forum* 43(2) [Mar.–Apr. 2017]

Posted September 29, 2017; Updated January 26, 2018 ¹

In accordance with USP's Rules and Procedures of the 2015-2020 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:
USP Executive Secretariat
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
execsec@usp.org

¹ The PF 43(2) IRA Commentary was updated on January 26, 2018 to include information on the previously deferred IRA for Levocetirizine Dihydrochloride.

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

- Amlodipine and Valsartan Tablets
- Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
- Levocetirizine Dihydrochloride
- Naproxen Sodium Tablets

No comments were received for the following proposals:

- Naproxen Sodium
- Pyridostigmine Bromide Tablets

Monograph/Sections: Amlodipine and Valsartan Tablets

Expert Committee: Chemical Medicines 2

No. of Commenters: 1

Expert Committee-initiated Change: The Expert Committee replaced the solvent used in the preparation of Standard solution under *Dissolution Test 2, Diluent* with *Medium* to be consistent with the validation data.

Monograph/Sections: Amlodipine, Valsartan, and Hydrochlorothiazide Tablets

Expert Committee: Chemical Medicines 2

No. of Commenters: 1

Comment Summary #2: The commenter recommended clarifying the mobile phase used for preparing the Sample stock solution,

Response: Comment incorporated. The Expert Committee clarified that Sample stock solution is prepared in Diluent and not Mobile phase.

Expert Committee-initiated Change: The Expert Committee replaced the solvent in the preparation of Standard solution under *Dissolution Test 2, Diluent* with *Medium* to be consistent with the validation data.

Monograph/Sections: Levocetirizine Dihydrochloride/Test for Enantiomeric Purity

Expert Committee: Chemical Medicines 5

No. of Commenters: 1

Comment Summary #1: The commenter requested that the proposed procedure be replaced with their in-house method because several known impurities and several impurities specific to their process either co-elute or are poorly resolved from levocetirizine or the S-enantiomer.

Response: Comment not incorporated. The Expert Committee determined that the proposed method is suitable for its intended use.

Monograph/Sections: Naproxen Sodium Tablets

Expert Committee: Chemical Medicines 6

No. of Commenters: 1

Comment Summary #1: The commenter recommended deleting the *Identification* test C for sodium as it interferes with the sodium in the excipient.

Response: Comment not incorporated. The Expert Committee will consider future revision upon receiving the supporting data.