



Commentary

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

September 29, 2017

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

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

- Amlodipine and Valsartan Tablets
- Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
- 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 Monographs 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 Monographs 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: Naproxen Sodium Tablets

Expert Committee: Chemical Medicines Monographs 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.