



Commentary

Interim Revision Announcements proposed in: *Pharmacopeial Forum 42(6) [Nov.–Dec. 2016]*

March 31, 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.

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

Monograph/Section: Topiramate/Multiple Sections
Expert Committee: Chemical Medicines Monographs 4
No. of Commenters: 1

Comment Summary #1: The commenter suggested that the detector temperature and column temperature should be the same in the tests for *Assay* and *Organic Impurities*.

Response: Comment not incorporated. The temperatures in the *Assay* and *Organic Impurities* sections are revised based on the inputs received from the sponsor.

Comment Summary #2: The commenter indicated that the resolution requirement is not necessary to determine the system suitability in the test for *Assay*.

Response: Comment not incorporated. The Expert Committee determined that the resolution between topiramate and topiramate related compound A is critical for establishing the system suitability.

Monograph/Sections: Almotriptan Malate/Limit of Almotriptan Related Compound D and Almotriptan N-Dimer
Expert Committee: Chemical Medicines Monographs 4
No. of Commenters: 1

Comment Summary #1: The commenter indicated that a range of migration times for 4-hydroxy-4-phenylpiperidine under *Parameter Set B* within *Table 1* may not be suitable. When the voltage is adjusted so that 4-hydroxy-4-phenylpiperidine migrates within 12-15 minutes some systems do not function properly.

Response: Comment incorporated. The statements about the migration time of 4-hydroxy-4-phenylpiperidine were removed from *Table 1*.