Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 38(6) [Nov.–Dec. 2012]**

August 9, 2013

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.

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No comments received for the following proposals
Citalopram Oral Solution
Citalopram Tablets

Monograph/Sections: Escitalopram Tablets/Multiple Sections
Expert Committee: Monographs—Small Molecules 4
No. of Commenters: 1
Comment Summary #1: The commenter requested adding a dissolution test for a drug product approved by the FDA. This new test (Dissolution Test 2) was validated using an Inertsil ODS-2 brand of L1 column and requires the use of USP Escitalopram Oxalate RS. The typical retention time for escitalopram is about 5.4 min.
Response: Comment incorporated.
Comment Summary #2: The commenter requested widening of the limit for any other individual unspecified impurity in the test for *Organic Impurities* from NMT 0.1% to NMT 0.20% for consistency with FDA-approved specifications.
Response: Comment incorporated.
Expert Committee-initiated Change #1: A statement clarifying that escitalopram is an optical isomer of citalopram was added to the Note within the *Definition* section.
Expert Committee-initiated Change #2: The redundant chemical information in *Table 1* was removed and the footnotes were renumbered accordingly.
Expert Committee-initiated Change #3: A labeling section was added to the monograph to support the inclusion of *Dissolution Test 2*.
Expert Committee-initiated Change #4: USP Escitalopram Oxalate RS was added to the USP Reference Standards section in support of Dissolution Test 2.