Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 40(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.

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

General Chapter/Sections: <41> Balances/Multiple
Expert Committee(s): General Chapters—Physical analysis
No. of Commenters: 6

Comment Summary #1: Two commenters indicated concerns that the use of a weight near minimum weight, combined with 2s vs. the previous 3s in the calculation and 0.10% vs. 0.1% for acceptance criteria may cause unforeseen and/or unreported failures even with new balances.

Response: Comment not incorporated. The weight used for the calculation of the standard deviation during the repeatability test does not need to be small. Although the change from 0.1% to 0.10% makes the requirement tighter, the change in the coverage factor from 3 to 2, makes the overall requirement essentially unchanged compared with the previous requirement.

Comment Summary # 2: Two commenters indicated that the term “desired smallest net weight” is not clearly defined.

Response: Comment incorporated.

Comment Summary #3: The commenter recommended retaining the reference to the nominal value and defining a range that would reduce the challenges presented by large and small test weights.

Response: Comment not incorporated. The new text will eliminate the possibility of passing the test by the use of a heavy weight.

Comment Summary #4: A commenter indicated that the fact that a smallest net weigh must be used seems to contradict with the statement about the independence of the repeatability with the weight used.

Response: Comment incorporated. It was clarified that the Standard deviation of the repeatability is independent of the weight used for the test.

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

Tacrolimus Capsules