***Commentary***

**Interim Revision Announcements proposed in:**
***Pharmacopeial Forum* 42(2) [Mar.–Apr. 2016]**

July 29, 2016

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.

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

**Monograph/Section:** Aspartic Acid/Impurities
**Expert Committee:** Monographs—Non-Botanical Dietary Supplements
**No. of Commenters:** 1
**Comment Summary # 1:** The commenter requested increasing the 6 N hydrochloric acid volume from “15 mL” to “20 mL” used in the *Sample solution* in the test for *Related Compounds*.
**Response:** Comment incorporated. “15 mL” was replaced with “15 mL–20 mL”.

**Monograph/Section**: Levothyroxine Sodium Tablets/Limit of Liothyronine Sodium
**Expert Committee**: Chemical Medicines Monographs 3
**No. of Commenters**: 1
**Comment Summary #1**: The commenter recommended retaining the Standard solution, because it is used to establish system suitability.
**Response**: Comment incorporated.

**Monograph/Section**: Liothyronine Sodium/Limit of Levothyroxine Sodium
**Expert Committee**: Chemical Medicines Monographs 3
**No. of Commenters**: 1
**Comment Summary #1**: The commenter recommended retaining the Standard solution, because it is used to establish system suitability.
**Response**: Comment incorporated.

**Monograph/Sections**: Tamsulosin Hydrochloride/Multiple Sections
**Expert Committee**: Chemical Medicines Monographs 3
**No. of Commenters**: 2
**Comment Summary #1**: The commenter indicated that they did not experience any technical issues with the existing *Assay* procedure, and requested to retain the existing *Assay* procedure using a flexible monograph approach.
**Response:** Comment not incorporated. No supporting information was provided to indicate that the updated *Assay* procedure is not suitable for all official substances.
**Comment Summary #2:** The commenter recommended revising the *Enantiomeric Purity* test to include acceptance criteria for relative standard deviation in the System suitability solution, to ensure the system performance.
**Response:** Comment not incorporated. The Expert Committee will consider future revisions to the monograph upon the receipt of supporting data.