



## ***Commentary***

### **Interim Revision Announcements proposed in: *Pharmacopeial Forum 42(5) [Sep.–Oct. 2016]***

January 27, 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.

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

**Monograph/Section:** Anastrozole Tablets/Identification  
**Expert Committee:** Chemical Medicines Monographs 3  
**No. of Commenters:** 2

**Comment Summary #1:** The commenter requested that the final dilution with potassium bromide be included in the preparation of pellet for analysis in the proposed *Identification A*.

**Response:** Comment incorporated.

**Comment Summary #2:** The commenter indicated that the impurity profile is different from what has been approved by FDA.

**Response:** Comment not incorporated. The Expert Committee determined that the comment is outside the scope of the revision. A future revision to the monograph will be considered upon receipt of the supporting data.