

**Commentary – *Pharmacopeial Forum* 34(1) January-February 2008**  
**Interim Revision Announcements**  
Revised June 30, 2008

Revision proposals published in *Pharmacopeial Forum* often elicit public comments that are forwarded to the appropriate Expert Committee for review and response. In accordance with the Rules and Procedures of the 2005-2010 Council of Experts, revision proposals can advance to official status with minor modifications, as needed, without requiring further public review. In such cases a summary of comments received and the appropriate Expert Committee's responses are published in the *Commentary* section of the USP website at the time the revision becomes official. For those proposals that require further revision and republication in *Pharmacopeial Forum*, a summary of the comments and the Expert Committee's responses will be included in the briefing that accompanies each article.

The *Commentary* section is not part of the official text of the monograph and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of the Expert Committee's response to public comments. If there is a difference between the contents of the *Commentary* section and the official monograph, the text of the official monograph prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary* section, shall prevail.

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**Pharmacopeial Forum 34(1)**

**Monograph/Section(s):** Alendronic Acid Tablets/Title

**Expert Committee(s):** Nomenclature

**No. of Commenters:** Not Applicable – Direct IRA

**Reason for Revision:** The title of this monograph was revised from “Alendronic Acid Tablets” to “Alendronate Sodium Tablets” to be consistent with USP’s *Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations*. The title “Alendronic Acid Tablets” was introduced as part of the new monograph in USP 28 and was scheduled to become official on May 1, 2008. The proposal to implement the title “Alendronic Acid Tablets” was subsequently canceled and use of the title “Alendronate Sodium Tablets” became mandatory on February 1, 2008.

**Monograph/Section(s):** Oxybutynin Chloride/Definition

**Expert Committee(s):** Monograph Development – Gastrointestinal, Renal, and Endocrine

**No. of Commenters:** 0

**Reason for Revision:** The upper limit in the Definition was revised from “not more than 101.0 percent” to “not more than 102.0 percent”, which is typical for chromatographic procedures and is consistent with changing the Assay methodology from titration to HPLC.