

**Commentary – *Pharmacopeial Forum* 35(2) March-April 2009
Interim Revision Announcements to *USP 31-NF 26*
Revised February 11, 2009**

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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Monograph/Section(s): Galantamine Tablets/Related Compounds
Expert Committee(s): Monograph Development-Psychiatric and Psychoactives
No. of Commenter(s): 0
Content Summary: No comments received.

Reason for Revision #1: The monograph was revised to include two new specified impurities, *N*-desmethylgalantamine and *O*-desmethylgalantamine, with a limit of “not more than 0.5%” for each compound to accommodate all approved products.

Reason for Revision #2: The limit for 6 β -hexahydrogalantamine was increased from “not more than 0.30%” to “not more than 0.75%.” A second trivial name, galantamine *N*-oxide, was added for this impurity to accommodate all products with marketing approval.

Reason for Revision #3: The limit specification “not more than 0.5% for 6 α -hexahydrogalantamine” was added. A second trivial name, epigalantamine, was added for this impurity.

Reason for Revision #4: For 6 β -octahydrogalantamine, a second trivial name, lycoramine, was added to accommodate all approved products.

Reason for Revision #5: The limit was increased for any individual unspecified degradation product from “not more than 0.20%” to “not more than 0.2%” to be consistent with the ICH Q3B.

Reason for Revision #6: The limit for total impurities was increased from “not more than 1.0%” to “not more than 1.5%” to accommodate all approved products.