USP–NF General Chapter <467> Residual Solvents / Organic Volatile Impurities

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This explanatory note is intended to inform users regarding upcoming revisions to General Chapter <467> Residual Solvents/Organic Volatile Impurities, the current status of the General Notices requirements, and the current organic volatile impurities (OVI) testing requirements.

Background

Beginning July 1, 2008, all drug substances, excipients, and products in the *USP–NF* are subject to relevant control of residual solvents, even when no test is specified in the individual monograph, according to the following statement in General Notices and Requirements (Tests and Assays section):

"Residual Solvents–The requirements are stated in Residual Solvents <467> together with information in Impurities in Official Articles <1086>. Thus all drug substances, excipients, and products are subject to relevant control of residual solvents, even when no test is specified in the individual monograph. The requirements have been aligned with the ICH guideline on this topic. If solvents are used during production, they are of suitable quality. In addition, the toxicity and residual level of each solvent are taken into consideration, and the solvents are limited according to the principles defined and the requirements specified in Residual Solvents <467>, using the general methods presented therein or other suitable methods. (Official July 1, 2008)"

The implementation date for this requirement was recently delayed from July 1, 2007 to July 1, 2008, pursuant to a Revision Bulletin. For more information on the delayed implementation date, see Delayed Implementation Date for General Chapter <467> Residual Solvents. Until July 1, 2008, users must meet only the requirements for Organic Volatile Impurities that are specified in individual monographs.

Revision Updates

General Chapter <467> is being revised in two ways.

First, a revised procedure for water-insoluble articles became official through an Interim Revision Announcement (IRA). The IRA was published in Pharmacopeial Forum 33(3) and became official on June 1, 2007.

Second, in response to comments received regarding the differences between the current version of <467> and the ICH Q3C Guidance, a revised draft of Residual Solvents <467> was published in PF 32(5). The General Chapters Expert Committee has made further changes to the proposed text after reviewing additional comments received during the comment period and has approved the revisions. This text was published as official in the second supplement to USP 30 in June 2007 and will become official on December 1, 2007.

Additional information

- Summary and Presentations from the USP/PDA Residual Solvents Educational Conference, January 18–19, 2007
- Frequently Asked Questions

Please submit comments or further inquiries on this topic to Horacio Pappa, Ph.D., Senior Scientist, at hp@usp.org or +1-301-816-8319.