
General Chapter <467> Organic Volatile Impurities/Residual Solvents—Implementation Date Delayed to July 2008

Type of Posting: Revision Bulletin

Posting Date: 15–Jun–2007

In accordance with the Rules and Procedures of the Council of Experts, this Revision Bulletin changes the implementation date of the General Notices statement on Residual Solvents from July 1, 2007, **to July 1, 2008**. This Revision Bulletin is effective as of this date and will be published as an IRA in Pharmacopeial Forum 33(5). Official text for the change also will appear in *USP 31–NF 26*, as follows:

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, 2007~~) (Official July 1, 2008).

Three additional changes relating to General Chapter <467> Residual Solvents are affected by this Revision Bulletin. These are:

- **Title Change:** On July 1, 2008, the title of General Chapter <467> will change from Organic Volatile Impurities to Residual Solvents.
- **Other Analytical Procedures:** The section in General Chapter <467> titled Other Analytical Procedures will be retained as official text until July 1, 2008.
- **Monographs** that contain the Test for Organic Volatile Impurities will keep this test as an official requirement until July 1, 2008. After that date, the General Notices statement will apply to all monographs.

Pharmaceutical manufacturers that adopt the requirements of General Chapter <467> Residual Solvents prior to July 1, 2008 are considered to

meet the monograph requirements for Organic Volatile Impurities. This approach also is suitable for other official articles.

Please direct any questions to Horacio Pappa, Ph.D., Senior Scientist (+1-301-816-8319 or hp@usp.org).

- [More information on Delayed Implementation for General Chapter <467> Residual Solvents](#)