

<467> Residual Solvents

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Expert Committee: General Chapters Chemical Analysis

This is an update to the [Compendial Notice](#) of February 22, 2019 related to the proposed Interim Revision Announcement in *Pharmacopeial Forum* 45(3) [May–June 2019].

The comment period for this revision ended on July 31, 2019. During the comment period there were further developments in the ICH Q3C Expert Working Group (EWG) regarding the PDE of Ethylene glycol.

Based on the EWG recommendation, the ICH Assembly decided at their June 5-6, 2019 meeting to revert the PDE of Ethylene glycol to 6.2 mg/day. Therefore, USP is canceling the proposed change in the PDE of Ethylene glycol. The PDE for Ethylene glycol will remain at current value of 6.2 mg/day.

Based on public comments, the implementation date for 1) reclassifying Methyl isobutyl ketone (MIBK) from Class 3 Residual Solvent to Class 2 Residual Solvent; and 2) introducing a new Class 3 Residual Solvent (Triethylamine); will be changed to December 1, 2020

The proposed revision that reflects the above changes will be available online on September 27, 2019 and will become official on November 1, 2019.

Should you have any questions, please contact Edmond Biba, Scientific Liaison to the General Chapters–Chemical Analysis Expert Committee (301–230–3270 or exb@usp.org).