

<467> Residual Solvents

Type of Posting: Notice of Intent to Revise

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Expert Committee: General Chapters–Chemical Analysis

In accordance with section 7.04(c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the General Chapters–Chemical Analysis Expert Committee intends to revise:

- <467> *Residual Solvents*

The purpose of the proposed revisions is to incorporate the recent updates in the ICH Q3C Residual Solvents Guidelines. The updates consist of: 1) reclassifying Methyl isobutyl ketone (MIBK) from Class 3 Residual Solvent to Class 2 Residual Solvent; 2) introducing a new Class 3 Residual Solvent (Triethylamine); and 3) correcting the PDE for Ethylene glycol from 6.2 mg/day to 3.1 mg/day.

It is anticipated that the proposed revisions will be published as a proposed Interim Revision Announcement in *Pharmaceutical Forum* 45(3) [May–June 2019]. The comment period for this revision ends on July 31, 2019. In the absence of any adverse comments the proposed IRA is anticipated to 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).