



**Proposed Sorbitol Solutions Method  
Posted on the USP Web site July 1, 2009-August 14, 2009**

**Summary of Informal Comments Received and Changes Made**

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On July 1, 2009, USP posted a proposed method for informal comments for Sorbitol Solution, Sorbitol Sorbitan Solution, and Noncrystallizing Sorbitol Solution to include a Limit of Diethylene Glycol and Ethylene Glycol in the Identification test. On the basis of comments received, the Expert Committee made the following changes to the proposed method:

1. The *Standard solution* section has been revised to read as below.  
**Standard solution:** 0.08 mg/mL of USP Diethylene Glycol RS and 0.08 mg/mL of USP Ethylene Glycol RS in *Diluent*.
2. In the *Sample solution* section, for clarity purposes, the phrase “Filter a portion of the test solution so obtained” has been replaced by “**Pass a portion of the supernatant layer obtained**”, add “about” before “3 min” to make the sentence read as “Vortex the flask for **about** 3 minutes after each addition of *Diluent*.” The Expert Committee has added a Note at the end of the *Sample solution* section to clarify the use of acetone in the test:  
**[NOTE—Acetone is used to precipitate sorbitol]**
3. The *Chromatographic system* section has been revised, under *Injection mode*, to: “Injection mode: Split 10:1” to “**Injection type: Split injection; Split ratio is about 10:1**”. In addition, delete “low pressure” in the following Note, to read as **[NOTE—A split liner, deactivated with glass wool, is used.]**
4. In the *System Suitability* section, one lab reported a large discrepancy for relative retention time of diethylene glycol. The Note has been revised to read as **[Note—Diethylene glycol elutes after ethylene glycol in the chromatogram.]**
5. In the *Acceptance criteria* section, clarify this section to indicate separate acceptance criteria for diethylene glycol and ethylene glycol. This section now reads as below.

**Acceptance criteria:**

**Diethylene Glycol:** The peak area of diethylene glycol in the *Sample solution* is not more than the peak area of diethylene glycol in the *Standard solution*, corresponding to not more than 0.10% of diethylene glycol in Sorbitol Solution.

**Ethylene Glycol:** The peak area of ethylene glycol in the *Sample solution* is not more than the peak area of ethylene glycol in the *Standard solution*, corresponding to not more than 0.10% of ethylene glycol in Sorbitol Solution.