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Sorbitol Solution

DEFINITION
Sorbitol Solution is an aqueous solution containing NLT 64.0% of D-sorbitol (C₆H₁₄O₆). The amounts of total sugars, other polyhydric alcohols, and any hexitol anhydrides, if detected, are not included in the requirements nor in the calculated amount as stated in [General Notices, 5.60.10 Other Impurities in USP and NF Articles](#).

IDENTIFICATION

- A.**
Sample solution: Dissolve 1.4 g of Sorbitol Solution in 75 mL of [water](#).
Analysis: Transfer 3 mL of the *Sample solution* to a 15-cm test tube. Add 3 mL of a freshly prepared solution of [catechol](#) (1 in 10), and mix. Add 6 mL of [sulfuric acid](#), mix again, and gently heat the tube in a flame for 30 s.
Acceptance criteria: A deep pink or wine-red color appears.
- B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the [Assay](#).
- C. LIMIT OF DIETHYLENE GLYCOL AND ETHYLENE GLYCOL**
Diluent: [Acetone](#) and [water](#) (96:4)
Standard solution: 0.08 mg/mL of [USP Diethylene Glycol RS](#) and 0.08 mg/mL of [USP Ethylene Glycol RS](#) in *Diluent*
Sample solution: Transfer 2.0 g of Sorbitol Solution to a 25-mL volumetric flask. Add 1.0 mL of *Diluent* to the flask, and mix on a vortex mixer for 3 min. Add the remaining *Diluent* to the flask to volume in 3 equal portions. Mix on a vortex mixer for about 3 min after each addition of *Diluent*. Pass a portion of the supernatant layer obtained through a 0.45-µm nylon filter. Discard the first 2 mL of the filtrate, and collect the rest of the filtrate for analysis. [NOTE—Acetone is used to precipitate sorbitol.]

Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 15-m fused-silica capillary column; 0.25-µm layer of phase [G46](#)
Temperatures
Detector: 300°
Injection port: 240°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
70	—	70	2
70	50	300	5

Carrier gas: Helium
Flow rate: 3.0 mL/min
Injection volume: 1.0 µL
Injection type: Split, split ratio 10:1. [NOTE—A split liner, deactivated with glass wool, is used.]
System suitability
Sample: *Standard solution*

[NOTE—Diethylene glycol elutes after ethylene glycol.]

Suitability requirements

Resolution: NLT 30 between ethylene glycol and diethylene glycol

Analysis

Samples: *Standard solution* and *Sample solution*

Based on the *Standard solution*, identify the peaks of ethylene glycol and diethylene glycol. Compare peak areas of ethylene glycol and diethylene glycol in the *Standard solution* and the *Sample solution*.

Acceptance criteria

Diethylene glycol: The peak area of diethylene glycol in the *Sample solution* is NMT the peak area of diethylene glycol in the *Standard solution*, corresponding to NMT 0.10% of diethylene glycol in Sorbitol Solution.

Ethylene glycol: The peak area of ethylene glycol in the *Sample solution* is NMT the peak area of ethylene glycol in the *Standard solution*, corresponding to NMT 0.10% of ethylene glycol in Sorbitol Solution.

ASSAY

PROCEDURE

Mobile phase: [Water](#)

System suitability solution: 4.8 mg/g of mannitol and 4.8 mg/g of [USP Sorbitol RS](#) in [water](#)

Standard solution: 4.8 mg/g of [USP Sorbitol RS](#) in [water](#)

Sample solution: 6.0 mg/g of Sorbitol Solution in [water](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 10-cm; packing [L34](#)

Temperatures

Detector: 35°

Column: 50 ± 2°

Flow rate: 0.7 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for mannitol and sorbitol are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between sorbitol and mannitol, *System suitability solution*

Relative standard deviation: NMT 2.0% for sorbitol, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of D-sorbitol ($C_6H_{14}O_6$) in the portion of Sorbitol Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of sorbitol from the *Sample solution*

r_S = peak response of sorbitol from the *Standard solution*

C_S = concentration of [USP Sorbitol RS](#) in the *Standard solution* (mg/g)

C_U = concentration of Sorbitol Solution in the *Sample solution* (mg/g)

Acceptance criteria: NLT 64.0%

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%, calculated on the anhydrous basis, determined on a 2-g portion

Change to read:

• **LIMIT OF NICKEL**

▲ [NOTE—When water is specified as the diluent, use deionized ultra-filtered water. Use of glass volumetric flasks is discouraged.]

Digest solution: Add 360 mL of [hydrochloric acid, ultratrace](#), and 240 mL of [nitric acid, ultratrace](#), to 1200 mL of water.

Blank solution: Add 40 mL of [nitric acid, ultratrace](#), to a 2000-mL volumetric flask, dilute with water to volume, and mix well.