# Maltitol Solution

**DEFINITION**

Maltitol Solution is a water solution containing, on the anhydrous basis, NLT 50.0% of D-maltitol ($C_{12}H_{24}O_{11}$) (w/w) and NMT 8.0% of D-sorbitol ($C_6H_{14}O_6$) (w/w). The amounts of total sugars, other polyhydric alcohols, and any polyol anhydrides, if detected, are not included in the requirements nor in the calculated amount under *Other Impurities.*

**IDENTIFICATION**

• **A. PROCEDURE**

**Sample:** 1.4 g of Maltitol Solution

**Analysis:** Dissolve the *Sample* in 75 mL of water. Transfer 3 mL of this solution to a 15-cm test tube, add 3 mL of freshly prepared catechol (1 in 10), and mix. Add 6 mL of sulfuric acid, mix, and gently heat the tube in a flame for about 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.*

***Add the following:***

•• **C. LIMIT OF DIETHYLENE GLYCOL AND ETHYLENE GLYCOL**

**Diluent:** Acetone and water (96:4)

**Standard stock solution:** 0.5 mg/mL of USP Diethylene Glycol RS and 0.5 mg/mL of USP Ethylene Glycol RS in *Diluent*

**Internal standard stock solution:** 0.5 mg/mL of 1,3-butanediol (internal standard) in *Diluent*

**Standard solution:** 0.04 mg/mL of USP Diethylene Glycol RS, 0.04 mg/mL of USP Ethylene Glycol RS, and 0.04 mg/mL of 1,3-butanediol, in *Diluent*, prepared from the *Standard stock solution* and *Internal standard stock solution*

**Sample solution:** Transfer 1.0 g of Maltitol Solution to a 25-mL volumetric flask. Add 1.0 mL of water to the flask and mix on a vortex mixer for 3 min. Add 2.0 mL of the *Internal standard stock solution* and 5 mL of *Diluent*, and mix on a vortex mixer for 3 min. Add the remaining *Diluent* to the flask to volume in two equal portions. Mix the content for about 3 min after each addition of *Diluent*. Pass a portion of the supernatant layer through a nylon filter of 0.45-µm pore size. Discard the first 2 mL of the filtrate, and collect the rest of the filtrate for analysis. [NOTE—Acetone is used to precipitate maltitol.]

**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

**Temperature**

**Detector:** 300°

**Injection port:** 240°

**Column:** See temperature program table below.

| 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 size:** 1.0 µL

**Injection type:** Split injection. The split ratio is about 10:1. [NOTE—A general purpose split/splitless, taper, glass wool, and deactivated liner is used.]

**System suitability**

**Sample:** *Standard solution*

[NOTE—See the relative retention time table below. Relative retention times are provided for information only, and the standards should be used to ensure appropriate peak identification.]

| Name | Relative Retention Time |
|---|---|
| Ethylene glycol | 1.0 |
| 1,3-Butanediol (internal standard) | 2.2 |
| Diethylene glycol | 2.8 |

**Suitability requirements**

**Resolution:** NLT 15 between ethylene glycol and 1,3-butanediol

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Based on the *Standard solution*, identify the peaks of ethylene glycol, 1,3-butanediol (internal standard), and diethylene glycol. Compare peak area ratios of ethylene glycol to the internal standard and of diethylene glycol to the internal standard in the *Standard solution* and *Sample solution*, respectively.

**Acceptance criteria**

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

**Ethylene glycol:** The peak area ratio of ethylene glycol to the internal standard in the *Sample solution* is NMT the peak area ratio of ethylene glycol to the internal standard in the *Standard solution*, corresponding to NMT 0.10% of ethylene glycol in Maltitol Solution.• (RB 1-Aug-2010)

**ASSAY**

• **PROCEDURE**

**Mobile phase:** Water

**Standard solution:** 10 mg/g of USP Maltitol RS and 1.6 mg/g of USP Sorbitol RS

**Sample solution:** 20 mg/g of Maltitol Solution in water

**Chromatographic system**

(See *Chromatography* ⟨621⟩*, System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Column:** 7.8-mm × 10-cm; packing L34

**Temperature**

**Column:** 60 ± 2°

**Detector:** 35°

**Flow rate:** 0.5 mL/min

**Injection size:** 10 µL

**System suitability**

**Sample:** *Standard solution*

[NOTE—The relative retention times for maltotriitol, maltitol, and sorbitol are 0.38, 0.48, and 1.0, respectively.]

**Suitability requirements**
**Tailing factor:** NMT 1.2 for maltitol and sorbitol
**Relative standard deviation:** NMT 2.0%
**Analysis**
**Samples:** *Standard solution* and *Sample solution*
Calculate the percentage, on the anhydrous basis, of $C_{12}H_{24}O_{11}$ and $C_6H_{14}O_6$ in the portion taken:

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

$r_U$ = peak response of D-maltitol or D-sorbitol from the *Sample solution*
$r_S$ = peak response of D-maltitol or D-sorbitol from the *Standard solution*
$C_S$ = concentration of the appropriate USP Reference Standard in the *Standard solution* (mg/g)
$C_U$ = concentration of Maltitol Solution in the *Sample solution* (mg/g)
W = percentage in the test for *Water Determination*

**Acceptance criteria:** NLT 50.0% of D-maltitol (w/w) and NMT 8.0% of D-sorbitol (w/w), on the anhydrous basis

## IMPURITIES

### Inorganic Impurities

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%, calculated on the anhydrous basis, determined on a 2-g portion
- **LIMIT OF NICKEL**

**Solution A:** 10 mg/mL of ammonium pyrrolidine dithiocarbamate
**Sample solution:** Dissolve and dilute 20.0 g of Maltitol Solution with diluted acetic acid to 100 mL. Add 2.0 mL of *Solution A* and 10.0 mL of methyl isobutyl ketone, and shake for 30 s. Protect from bright light. Allow the two layers to separate, and use the methyl isobutyl ketone layer.
**Standard solutions:** Prepare as directed for the *Sample solution*, except to prepare three solutions by adding 0.5, 1.0, and 1.5 mL of nickel standard solution TS.
**Blank solution:** Prepare as directed for the *Sample solution*, except to omit the use of the Maltitol Solution.
**Spectrometric conditions**
(See *Spectrophotometry and Light-Scattering* ⟨851⟩.)
**Mode:** Atomic absorption spectrophotometry
**Analytical wavelength:** 232.0 nm (maximum absorbance)
**Lamp:** Nickel hollow-cathode
**Flame:** Air–acetylene
**Analysis**
**Samples:** *Sample solution*, *Standard solutions*, and *Blank solution*
Set the instrument to zero using the *Blank solution*. Concomitantly determine the absorbances of the *Standard solutions* and the *Sample solution* at least three times each. Record the average of the steady readings for each of the *Standard solutions* and the *Sample solution*. Between each measurement, aspirate the *Blank solution*, and ascertain that the reading returns to zero. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the added quantity of nickel. Extrapolate the line joining the points on the graph until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel in the *Sample solution*.
**Acceptance criteria:** NMT 1 ppm, calculated on the anhydrous basis

### Organic Impurities

- **PROCEDURE: REDUCING SUGARS**

**Sample:** An amount of Maltitol Solution equivalent to 3.3 g on the anhydrous basis
**Analysis:** To the *Sample* add 3 mL of water, 20.0 mL of cupric citrate TS, and a few glass beads. Heat so that boiling begins after 4 min, and maintain boiling for 3 min. Cool rapidly, and add 40 mL of diluted acetic acid, 60 mL of water, and 20.0 mL of 0.05 N iodine VS. With continuous shaking, add 25 mL of a mixture of 6 mL of hydrochloric acid and 94 mL of water. When the precipitate has dissolved, titrate the excess of iodine with 0.05 N sodium thiosulfate VS using 2 mL of starch TS, added toward the end of the titration, as an indicator.
[NOTE—The amount determined in this test is not included in the calculated amount under *Other Impurities*.]
**Acceptance criteria:** NLT 12.8 mL of 0.05 N sodium thiosulfate VS is required, corresponding to NMT 0.3% of reducing sugars, on the anhydrous basis, as glucose.

## SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS ⟨61⟩** and **TESTS FOR SPECIFIC MICROORGANISMS ⟨62⟩:** The total aerobic microbial count using the *Plate Method* is NMT 1000 cfu/mL, and the total combined molds and yeasts count is NMT 100 cfu/mL.
- **pH ⟨791⟩:** 5.0–7.5, in a 14% (w/w) solution of Maltitol Solution in carbon dioxide-free water
- **WATER DETERMINATION,** *Method I* **⟨921⟩:** NMT 31.5%

## ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. No storage requirements are specified.

***Change to read:***

- **USP REFERENCE STANDARDS ⟨11⟩**

•USP Diethylene Glycol RS
USP Ethylene Glycol RS• (RB 1-Aug-2010)
USP Maltitol RS
USP Sorbitol RS