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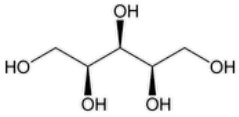
Xylitol



$C_5H_{12}O_5$ 152.15
Xylitol.

DEFINITION

Xylitol contains NLT 98.5% and NMT 101.0% of $C_5H_{12}O_5$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Undried

• **B.** The retention time of the xylitol peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (20:80)

System suitability solution: 2.5 mg/mL of USP Galactitol RS and 25 mg/mL of USP Xylitol RS in *Mobile phase*

Standard solution: 25 mg/mL of USP Xylitol RS in *Mobile phase*

Sample solution: 25 mg/mL of Xylitol in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 192 nm

Column: 8.0-mm × 30-cm; 7-µm packing L34

Column temperature: 80°

Flow rate: 0.5 mL/min

Injection size: 25 µL

System suitability

Sample: *System suitability solution* and *Standard solution*

[Note—The relative retention times for xylitol and galactitol are about 1.0 and 1.10, respectively.]

Suitability requirements

Resolution: NLT 2.0 between galactitol and xylitol, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of xylitol ($C_5H_{12}O_5$) in the portion of sample taken:

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

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

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

C_S = concentration of USP Xylitol RS in the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.0% on the anhydrous basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.5%

• **Reducing Sugars**

Sample: 500 mg

Analysis: Dissolve the *Sample* in 2.0 mL of water in a 10-mL conical flask. Into a similar flask, pipet 2 mL of a 0.5 mg/mL dextrose solution. To each flask add 1 mL of alkaline cupric tartrate TS, heat to boiling, and cool.

Acceptance criteria: Any turbidity in the xylitol flask is NMT that in the dextrose flask, in which a reddish-brown precipitate forms (0.2% reducing sugars, as dextrose).

• **Limit of Other Polyols**

Mobile phase: Acetonitrile and water (20:80)

System suitability solution: 0.5 mg/mL each of USP L-Arabinitol RS, USP Galactitol RS, USP Mannitol RS, and USP Sorbitol RS, and 100 mg/mL of USP Xylitol RS in *Mobile phase*

Standard solution: 0.5 mg/mL each of USP L-Arabinitol RS, USP Galactitol RS, USP Mannitol RS, and USP Sorbitol RS in *Mobile phase*

Sample solution: 100 mg/mL of Xylitol in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 192 nm

Column: 8.0-mm × 30-cm; 7-µm packing L34

Column temperature: 80°

Flow rate: 0.5 mL/min

Injection size: 25 µL

System suitability

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

[Note—The relative retention times for L-arabinitol, mannitol, xylitol, galactitol, and sorbitol are about 0.76, 0.81, 1.0, 1.12, and 1.22, respectively.]

Suitability requirements

Resolution: NLT 1.5 between all adjacent polyol peaks, *System suitability solution*

Relative standard deviation: NMT 5.0% for the galactitol peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each polyol (L-arabinitol, galactitol, mannitol, or sorbitol) in the portion of sample taken:

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

r_U = peak response of the individual polyol from the *Sample solution*

r_S = peak response of the individual polyol from the *Standard solution*

C_S = concentration of the individual polyol in the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: The sum of the polyols is NMT 2.0%, calculated on the anhydrous basis.

SPECIFIC TESTS

• **Water Determination, *Method I* ⟨921⟩:** NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

- **USP Reference Standards** ⟨11⟩

USP L-Arabinitol RS
USP Galactitol RS
USP Mannitol RS
USP Sorbitol RS
USP Xylitol RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
XYLITOL	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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