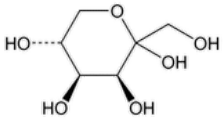
Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: NF Monographs
DocId: GUID-E2BD4C97-1824-461B-A06F-FF86176FC15E_1_en-US
DOI: https://doi.org/10.31003/USPNF_M937_01_01
DOI Ref: izc42

Tagatose



$C_6H_{12}O_6$ 180.16

D-Tagatose;

D-*lyxo*-Hexulose CAS RN®: 87-81-0.

DEFINITION

Tagatose is a ketohexose, an epimer of D-fructose inverted at C-4. It is obtained from D-galactose by isomerization under alkaline conditions in the presence of calcium. It contains NLT 98.0% of tagatose ($C_6H_{12}O_6$), calculated on the dried basis.

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** It meets the requirements of the test for *Optical Rotation ⟨781⟩, Specific Rotation*.
- **C.**

Sample solution: 200 mg/mL of Tagatose

Analysis: Add 3 mL of the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.

Acceptance criteria: A copious red precipitate of cuprous oxide is formed.

ASSAY

- **Procedure**

Mobile phase: 0.05 mg/mL of calcium acetate

Standard solution: 5 mg/mL of USP Tagatose RS. Pass through a filter of 0.2-µm pore size.

Sample solution: 5 mg/mL of Tagatose, previously dried. Pass through a filter of 0.2-µm pore size.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm; 9-µm packing L19

Column temperature: 85°

Flow rate: 0.6 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0% of replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tagatose ($C_6H_{12}O_6$) in the portion of Tagatose taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: NLT 98.0% on the dried basis

IMPURITIES

• **Limit of Lead**

Sample solution: 2.5 g of Tagatose dissolved in a mixture of 4 mL of sulfuric acid and 5 mL of hydrochloric acid. Dilute with water to 50 mL.

Standard stock solution A: Dissolve 1.60 g of lead nitrate in diluted nitric acid (10 mL of nitric acid diluted with 20 mL water, boiled to remove nitrous fumes, and cooled), and dilute with water to 1000 mL.

Standard stock solution B: *Standard stock solution A* and water (1:50). [Note—This solution contains the equivalent of 20 µg/mL of lead.]

Standard solutions: To a series of 100-mL volumetric flasks pipet 0, 1, 2, 3, 4, and 5 mL of *Standard stock solution B*, and dilute with water to about 50 mL. Add 8 mL of sulfuric acid and 10 mL of hydrochloric acid to each flask, shake to dissolve, and dilute with water to volume. [Note—These solutions contain 0, 0.2, 0.4, 0.6, 0.8, and 1.0 µg/mL of lead, respectively.]

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption

Analytical wavelength: 283.3 nm

Analysis

Samples: *Standard solutions* and *Sample solution*

Concomitantly determine the absorbances of the *Standard solutions* and the *Sample solution*. Plot the absorbances of the *Standard solutions* versus the concentration of lead. Using this graph, determine the concentration of lead in the *Sample solution*.

Acceptance criteria: NMT 1 ppm

SPECIFIC TESTS

• **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*. The total aerobic microbial count does not exceed 1000 cfu/g, and the total combined molds and yeasts count does not exceed 100 cfu/g.

• **Melting Range or Temperature,** *Class I* ⟨741⟩**:** 133°–144°

• **Optical Rotation,** *Specific Rotation* ⟨781⟩**:** −4° to −7°

Sample solution: 10 mg/mL

• **Loss on Drying** ⟨731⟩**:** Dry a sample at 102° for 2 h: it loses NMT 0.5% of its weight

• **Articles of Botanical Origin,** *Total Ash* ⟨561⟩**:** NMT 0.1%, determined on a 1.0-g specimen

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at room temperature.

• **USP Reference Standards** ⟨11⟩

USP Tagatose RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 31(3)

Current DocID: GUID-E2BD4C97-1824-461B-A06F-FF86176FC15E_1_en-US
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