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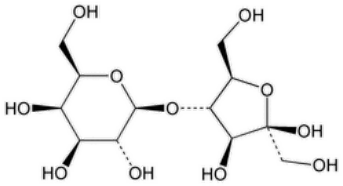
Lactulose Concentrate



$C_{12}H_{22}O_{11}$ 342.30

D-Fructose, 4-*O*-β-D-galactopyranosyl-;

4-*O*-β-D-Galactopyranosyl-D-fructofuranose CAS RN®: 4618-18-2.

DEFINITION

Lactulose Concentrate is a solution of sugars prepared from Lactose. It consists principally of lactulose together with minor quantities of lactose and galactose, and traces of other related sugars and water. It contains NLT 95.0% and NMT 105.0% of the labeled amount of lactulose ($C_{12}H_{22}O_{11}$). It contains no added substances.

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.**

Sample solution: Dilute a portion of Concentrate with water (1 in 20).

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

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

ASSAY

- **Procedure**

Buffer: 1.15 g/L of monobasic sodium phosphate in water

Mobile phase: Acetonitrile and *Buffer* (82:18). Ensure that the concentration of acetonitrile in the *Mobile phase* is between 78% and 85% to obtain appropriate retention times.

Standard solution: 40 mg/mL of USP Lactulose RS, 4.8 mg/mL of USP Anhydrous Lactose RS, and 3.2 mg/mL of USP Epilactose RS in a mixture of acetonitrile and water (1:1)

Sample solution: Nominally equivalent to 40 mg/mL of lactulose prepared as follows. Transfer a quantity of Concentrate containing 2.0 g of lactulose to a 50-mL volumetric flask, and dissolve in 20 mL of water. Add 25.0 mL of acetonitrile, allow the solution to reach ambient temperature, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 4.6-mm × 15-cm; 3-µm packing L8

Temperatures

Column: 40 ± 1°

Detector: 40 ± 1°

Flow rate: 1.3 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times are given in *Table 1*.]

Suitability requirements

Resolution: NLT 1.5 between lactulose and lactose; NLT 0.9 between lactulose and epilactose

Relative standard deviation: NMT 2.0% for the main peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lactulose ($C_{12}H_{22}O_{11}$) in the portion of Concentrate 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 Lactulose RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.1%
- **Organic Impurities**

Buffer, Mobile phase, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*. To evaluate the *Suitability requirements*, use the *Standard solution* prepared as directed in the *Assay*.

Standard solution: 6.4 mg/mL of USP Galactose RS, 4.8 mg/mL of USP Anhydrous Lactose RS, 3.2 mg/mL of USP Epilactose RS, 1.2 mg/mL of USP Tagatose RS, and 0.4 mg/mL of USP Fructose RS in a mixture of acetonitrile and water (1:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of galactose, lactose, epilactose, tagatose, and fructose, if found, in the portion of Concentrate taken:

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

r_U = peak response of the relevant related compound from the *Sample solution*

r_S = peak response of the relevant related compound from the *Standard solution*

C_S = concentration of the relevant USP Reference Standard in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Tagatose	0.30	4
Fructose	0.34	1
Galactose	0.47	16
Epilactose	0.90	8
Lactulose	1.0	—
Lactose	1.17	12

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, preferably at a temperature between 2° and 30°. Avoid subfreezing temperatures.

• **Labeling:** The label states that this article is not intended for direct administration to humans or animals.

• **USP Reference Standards** ⟨11⟩

USP Epilactose RS
USP Fructose RS
USP Galactose RS
USP Anhydrous Lactose RS
USP Lactulose RS
USP Tagatose RS

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

Topic/Question	Contact	Expert Committee
LACTULOSE CONCENTRATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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