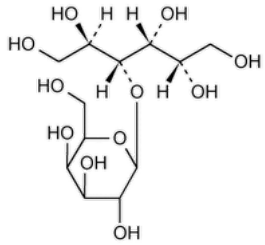
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-3C5A4EF1-35EC-498A-8DCE-F197064D453D_4_en-US
DOI: https://doi.org/10.31003/USPNF_M44100_04_01
DOI Ref: xvg5o

Lactitol



$C_{12}H_{24}O_{11}$ 344.31
$C_{12}H_{24}O_{11} \cdot H_2O$ 362.34
$C_{12}H_{24}O_{11} \cdot 2H_2O$ 380.35

4-*O*-β-D-Galactopyranosyl-D-glucitol CAS RN®: 585-86-4.

Monohydrate CAS RN®: 81025-04-9.

Dihydrate CAS RN®: 81025-03-8.

DEFINITION

Lactitol contains NLT 98.0% and NMT 101.0% of $C_{12}H_{24}O_{11}$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

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

ASSAY

• **Procedure**

Mobile phase: Water

Standard solution: 10.0 mg/mL of USP Lactitol RS

Sample solution: 10.0 mg/mL of Lactitol

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm; packing L34

Column temperature: 85°

Flow rate: 0.7 mL/min

Injection size: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0% for lactitol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of lactitol ($C_{12}H_{24}O_{11}$) in the portion of Lactitol 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 Lactitol RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–101.0% on the anhydrous basis

IMPURITIES

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

• **Related Compounds**

Standard solution: 0.3 mg/mL of USP Lactitol RS

Sample solution: Prepare as directed in the *Assay*.

Chromatographic system: Proceed as directed in the *Assay*.

System suitability

Sample: *Standard solution*

[Note—The relative retention times for lactose, glucose, galactose, lactulitol, lactitol, galactitol, and sorbitol are about 0.53, 0.58, 0.67, 0.72, 1.0, 1.55, and 1.68, respectively.]

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of galactitol, sorbitol, lactulitol, lactose, glucose, and galactose in the portion of Lactitol taken:

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

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

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

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

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

Acceptance criteria: The total of the percentages of all related compounds is NMT 1.5%.

• **Reducing Sugars**

Standard solution: Pipet 2 mL of a dextrose solution containing 0.5 mg/mL into a 10-mL conical flask.

Sample solution: Disolve 500 mg in 2.0 mL of water in a 10-mL conical flask.

Analysis: Concomitantly add 1 mL of alkaline cupric tartrate TS to each solution, heat to boiling, and cool.

Acceptance criteria: NMT 0.2%, calculated as dextrose. The *Sample solution* shows no more turbidity than that produced in the *Standard solution*, in which a reddish brown precipitate forms.

SPECIFIC TESTS

• **Water Determination, *Method I* ⟨921⟩:** For the monohydrate form, 4.5%–5.5%; for the dihydrate form, 9.5%–10.5%; and for the anhydrous form, NMT 0.5%.

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Label it to indicate whether it is the monohydrate, the dihydrate, or the anhydrous form.

• **USP Reference Standards ⟨11⟩**
USP Lactitol RS

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

Topic/Question	Contact	Expert Committee
LACTITOL	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 31(4)

Current DocID: GUID-3C5A4EF1-35EC-498A-8DCE-F197064D453D_4_en-US

DOI: https://doi.org/10.31003/USPNF_M44100_04_01

DOI ref: xvg5o