

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: NF Monographs
DocId: GUID-301AA92E-BA95-4460-A497-25FFB5381844_2_en-US
DOI: https://doi.org/10.31003/USPNF_M78680_02_01
DOI Ref: 8f5yp

© 2025 USPC
Do not distribute

Confectioner's Sugar

DEFINITION

Confectioner's Sugar is Sucrose ground together with corn starch to a fine powder. It contains NLT 95.0% of sucrose ($C_{12}H_{22}O_{11}$), calculated on the dried basis.

IDENTIFICATION

- A.**
Sample solution: Transfer 20 g to a 100-mL volumetric flask, add 80 mL of water, shake to dissolve the sucrose, and then add water to volume. Separate the solubilized sucrose from the insoluble starch component by filtration until the filtrate is clear. Use the insoluble portion for the *Identification* test, and use the freshly prepared, clear filtrate in the *Impurities* tests for [Chloride and Sulfate \(221\)](#), [Chloride](#) and [Chloride and Sulfate \(221\)](#), [Sulfate](#) and for [Calcium](#); and in *Specific Tests* for [Optical Rotation \(781\)](#), [Specific Rotation](#).
Analysis: To the water slurry of the insoluble portion add iodine TS.
Acceptance criteria: A reddish-violet to deep blue color is produced.
- B.** It meets the requirements of the test for [Optical Rotation \(781\)](#), [Specific Rotation](#) in *Specific Tests*.

ASSAY

- CONTENT OF SUCROSE**
Mobile phase: Acetonitrile and water (80:20, v/v)
System suitability solution: Prepare an aqueous solution containing 20 mg/mL of sucrose, 1.0 mg/mL of dextrose (glucose), 0.6 mg/mL of fructose, 0.6 mg/mL of maltose, and 0.8 mg/mL of lactose using [USP Sucrose RS](#), [USP Dextrose RS](#), [USP Fructose RS](#), [USP Maltose Monohydrate RS](#), and [USP Anhydrous Lactose RS](#).
Standard solution: Dissolve [USP Sucrose RS](#) in water to obtain a solution having a concentration of about 20 mg/mL of sucrose.
Sample solution: 20 mg/mL of Confectioner's Sugar in water. Pass the solution through a 0.2-µm nylon syringe filter.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: Refractive index
Column: 4.6-mm × 15-cm; 5-µm packing L8
Temperatures
Column: 45°
Detector: 40°
Flow rate: 2.0 mL/min
Injection volume: 15 µL
System suitability
Samples: *System suitability solution* and *Standard solution*
[NOTE—For relative retention times, see [Table 1](#).]

Table 1

Name	Relative Retention Time
Fructose	0.5

Name	Relative Retention Time
Dextrose (glucose)	0.6
Sucrose	1.0
Maltose	1.3
Lactose	1.5

Suitability requirements

Resolution: NLT 1.3 between all adjacent peaks, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate, on the dried basis, the percentage of sucrose ($C_{12}H_{22}O_{11}$) in the portion of Confectioner's Sugar 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 Sucrose RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Confectioner's Sugar in the *Sample solution* (mg/mL)

Acceptance criteria: NLT 95.0% of sucrose on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.08%

- [CHLORIDE AND SULFATE, Chloride \(221\)](#)

Standard solution: 0.40 mL of 0.020 N hydrochloric acid

Sample solution: 10 mL of the clear filtrate from *Identification* test A

Acceptance criteria: 0.014%; the *Sample solution* shows no more chloride than the *Standard solution*.

- [CHLORIDE AND SULFATE, Sulfate \(221\)](#)

Standard solution: 0.30 mL of 0.020 N sulfuric acid

Sample solution: 25 mL of the clear filtrate from *Identification* test A

Acceptance criteria: 0.006%; the *Sample solution* shows no more sulfate than the *Standard solution*.

- **CALCIUM**

Sample solution: 5 mL of the clear filtrate from *Identification* test A

Analysis: To the *Sample solution* add 5 mL of water and 1 mL of ammonium oxalate TS.

Acceptance criteria: The *Sample solution* remains clear for NLT 1 min.

SPECIFIC TESTS

- [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): The total aerobic microbial count does not exceed 10^3 cfu/g, and the total combined molds and yeasts count does not exceed 10^2 cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 1.0%

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)

Sample solution: Use the clear filtrate from *Identification* test A.

Acceptance criteria: NLT +62.6° corresponding to NLT 95.0% of sucrose ($C_{12}H_{22}O_{11}$), calculated on the dried basis

