

Status: Currently Official on 10-Feb-2022
Official Date: Official as of 01-Jan-2018
Document Type: NF Monographs
DocId: GUID-301A4A3E-BA92-44E0-A493-52FFB2381844~3~en-US
DOI: https://doi.org/10.31003/USP-NF-M38980-05-01
DOI Ref: 812yb

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Confectioner's Sugar

DEFINITION

Confectioner's Sugar is sucrose ground together with corn starch to a fine powder. It contains NLT 92.0% 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 [Cyanide and Sulfate \(321\)](#), [Cyanide and Sulfate \(321\)](#), [Sulfate \(321\)](#), and for Calcium, and in Specific Tests for [Optical Rotation \(381\)](#), [Specific Rotation](#)

Analysis: To the water slurry of the insoluble portion add iodine T2.
Acceptance criteria: A reddish-violet to deep blue color is produced.

• B. It meets the requirements of the test for [Optical Rotation \(381\)](#), [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 0.5-µm nylon syringe filter.

Chromatographic system

(see [Chromatography \(321\)](#), [System Suitability](#))

Mode: LC

Detector: Refractive index

Column: 4.6-mm × 12-cm; 2-µm packing L8

Temperatures

Column: 42°

Detector: 40°

Flow rate: 2.0 mL/min

Injection volume: 12 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	0.2

Name	Relative Retention Time
Dextrose (glucose)	0.9
Sucrose	1.0
Maltose	1.3
Lactose	1.6

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 ($C_6H_{12}O_{11}$) in the portion of Confectioner's Sugar taken:

$$\text{Result} = (L_1/L_2) \times (C_2/C_1) \times 100$$

L_1 = peak response from the Sample solution

L_2 = peak response from the Standard solution

C_2 = concentration of sucrose in the Standard solution (mg/mL)

C_1 = concentration of Confectioner's Sugar in the Sample solution (mg/mL)

Acceptance criteria: NLT 92.0% of sucrose on the dried basis

IDENTIFICATION

- RESIDUE ON IGNITION (SR):** NMT 0.08%

- CHLORIDE AND SULFATE (SR):**

Standard solution: 0.40 mL of 0.050 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 (SR):**

Standard solution: 0.30 mL of 0.050 N sulfuric acid

Sample solution: 52 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: 2 mL of the clear filtrate from Identification test A

Analysis: To the Sample solution add 2 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 (SR)** and **TESTS FOR SPECIFIED MICROORGANISMS (SR):** The total aerobic microbial count does not exceed 10^6 cfu/g, and the total combined molds and yeasts count does not exceed 10^3 cfu/g. It meets the requirements of the tests for absence of salmonella species and Escherichia coli.

- LOSS ON DRYING (SR)**

Analysis: Dry at 102° for 4 h.

Acceptance criteria: NMT 1.0%

- OPTICAL ROTATION (SR):**

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

Acceptance criteria: NLT +62.5°, corresponding to NLT 92.0% of sucrose ($C_6H_{12}O_{11}$), calculated on the dried basis

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS (11).**
 - USP Anhydrous Lactose RS
 - USP Dextrose RS
 - USP Fructose RS
 - USP Maltose Monohydrate RS
 - USP Sucrose RS

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

Topic/Question	Contact	Expert Committee
CONFECTIONER'S SUGAR	DOCUMENTS & REGULATORY SUPPORT	2ES050 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RS.TECH@usp.org	2ES050 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(6)

CURRENT DOCID: [CUID-301AA3E-B4d2-44e0-84d1-52EEB2381844-5-EN-US](#)
PREVIOUS DOCID: [CUID-301AA3E-B4d2-44e0-84d1-52EEB2381844-1-EN-US](#)
DOI: [https://doi.org/10.31003/USP.NF.M38e80-05-01](#)
DOI ref: [822yb](#)

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