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Compressible Sugar

DEFINITION

Compressible Sugar contains NLT 95.0% and NMT 98.0% of sucrose ($C_{12}H_{22}O_{11}$) on the dried basis. It may contain starch, maltodextrin, or invert sugar and may contain a suitable lubricant.

IDENTIFICATION

• **A.** It meets the requirements of the test for *Specific Rotation* in *Specific Tests*.

Change to read:

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

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 Compressible 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
Dextrose (glucose)	0.6
Sucrose	1.0
Maltose	1.3

Name	Relative Retention Time
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 Compressible 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 Compressible Sugar in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–98.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Chloride and Sulfate,** *Chloride*⟨221⟩

Standard solution: 0.40 mL of 0.020 N hydrochloric acid

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 any insoluble matter by filtration until the filtrate is clear, and use the freshly prepared, clear filtrate.

Acceptance criteria: 0.014%; a 10-mL portion of the *Sample solution* shows no more chloride than the *Standard solution*.

• **Chloride and Sulfate,** *Sulfate*⟨221⟩

Standard solution: 0.50 mL of 0.020 N sulfuric acid

Sample solution: 25 mL of the *Sample solution* from the test for *Chloride and Sulfate ⟨221⟩, Chloride*

Acceptance criteria: 0.010%; the *Sample solution* shows no more sulfate than the *Standard solution*.

Change to read:

• **Limit of Calcium** ▲▲ (ERR 1-Jun-2018)

Sample solution: 5 mL of the *Sample solution* from the test for *Chloride and Sulfate ⟨221⟩, Chloride*

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

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

• **Limit of Dextrose (Glucose), Fructose, Maltose, and Lactose**

Mobile phase, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the test for *Content of Sucrose* in the *Assay*.

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for fructose, dextrose (glucose), sucrose, maltose, and lactose are 0.5, 0.6, 1.0, 1.3, and 1.5, respectively.]

Suitability requirements

Resolution: NLT 1.3 between all adjacent peaks

Acceptance criteria: The sum of the peak areas for dextrose, fructose, maltose, and lactose from the *Sample solution* is less than one third of the sum of the peak areas for dextrose, fructose, maltose, and lactose from the *System suitability solution*, corresponding to NMT 5% for the sum of dextrose, fructose, maltose, and lactose.

SPECIFIC TESTS

• **Specific Rotation**

Sample solution: Transfer 26.0 g of Compressible Sugar, previously dried, to a 100-mL volumetric flask. Add 0.3 mL of a saturated aqueous solution of lead acetate, shake with 90 mL of water, and dilute with water to volume. Distribute evenly on the surface of a sheet of medium-fast filter paper 8 g of chromatographic siliceous earth suitable for column partition chromatography (see *Reagents, Indicators, and Solutions—Reagents*), and filter the solution, with the aid of vacuum, discarding the first 20 mL of the filtrate.

Instrumental conditions

(See *Optical Rotation* ⟨781⟩.)

Mode: Specific rotation

Temperature: 20°

Analysis

Uninverted solution: Pipet 25 mL of the *Sample solution* into a 50-mL volumetric flask. Cool to 20°, and dilute with water to volume at 20°. Maintain a temperature of 20° for 30 min.

Acid-inverted solution: Pipet 25 mL of the *Sample solution* into a 50-mL volumetric flask. Slowly add 6 mL of dilute hydrochloric acid (1 in 2) while rotating it, dilute with water nearly to volume, and mix. Place the flask in a water bath maintained at a temperature of 60°, continuously shake the flask in the bath for 3 min, and allow the flask to remain in the bath for a total of 10 min. Immediately cool to 20° by plunging the flask into a cold bath, and dilute with water to volume at 20°. Maintain the flask at a temperature of 20° for 30 min. Determine the specific rotation of the *Uninverted solution* and *Acid-inverted solution* at 20°.

Acceptance criteria

The specific rotation determined from the *Uninverted solution*: 62.6°–73.4°

The specific rotation determined from the *Acid-inverted solution*: Levorotatory

• **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 the absence of *Salmonella* species and *Escherichia coli*.

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Label it to indicate the name and amount of any added lubricant.

• **USP Reference Standards** ⟨11⟩

USP Anhydrous Lactose RS
USP Compressible Sugar 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
COMPRESSIBLE SUGAR	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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