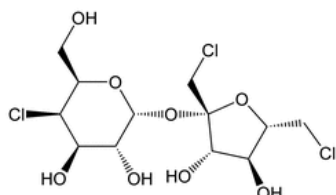


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Sucralose



$C_{12}H_{19}Cl_3O_8$ 397.63

1,6-Dichloro-1,6-dideoxy- β -D-fructofuranosyl-4-chloro-4-deoxy- α -D-galactopyranoside;

1',4,6'-Trichlorogalactosucrose CAS RN®: 56038-13-2.

DEFINITION

Sucralose contains NLT 98.0% and NMT 102.0% of sucralose ($C_{12}H_{19}Cl_3O_8$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B.** The retention time of the principal peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** The R_f value of the principal spot of the *Sample solution* corresponds to that of *Standard solution A*, as obtained in the test for *Related Compounds*.

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Acetonitrile](#) and [water](#) (3:17)

Standard solution: 1 mg/mL of [USP Sucralose RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Sucralose in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: 8-mm $\times$ 10-cm; $\blacktriangle$ 5- μ m $\blacktriangle$ (NF 1-Dec-2023) packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

[NOTE—The retention time of sucralose is about 9 min.]

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sucralose ($C_{12}H_{19}Cl_3O_8$) in the portion of Sucralose taken:

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

r_U = peak response of sucralose from the *Sample solution*

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

C_S = concentration of [USP Sucralose RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.7%

Change to read:

- **LIMIT OF METHANOL**

▲ **Standard stock solution:** 1000 µg/mL of [methanol](#) in [water](#)

Standard solution: Transfer 1.000 g of Sucralose to a 22-mL headspace vial. Add 4.0 mL of 10% (w/v) [sodium chloride](#) solution. Add 1.00 mL of the *Standard stock solution*. Crimp a cap with a Teflon seal tightly onto the vial, and mix the solution well.

Sample solution: Add 1.000 g of Sucralose to a 22-mL headspace vial. Add 4.0 mL of a 10% (w/v) [sodium chloride](#) solution. Add 1.00 mL of [water](#). Crimp a cap with a Teflon seal tightly onto the vial, and mix the solution well.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC with balanced-pressure headspace sampler

Detector: Flame ionization

Column: 0.32-mm × 30-m; 1.0-µm layer of phase [G16](#)

Temperatures

Injection port: 110°

Detector: 250°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	0	50	3
50	10	80	0
80	50	230	10

Carrier gas: Helium

Headspace sampler

[NOTE—The capillary column is installed through the GC inlet and through the transfer line to give on-column injection.]

Temperatures

Equilibration: 90°

Needle: 100°

Transfer line: 110°

Times

Equilibration: 10 min

Pressurization: 3.0 min

Withdrawal: 0.5 min

Injection: 0.15 min

Cycle: 25 min

Sampler delivery system: Helium set at 90 psi (not to exceed 100 psi)

System suitability

Sample: *Standard solution*

Suitability requirements**Relative standard deviation:** NMT 10.0%**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of methanol in the portion of Sucralose taken:

$$\text{Result} = (r_U \times W_S) / [(r_S - r_U) \times W_U] \times 100$$

 r_U = peak area of methanol from the *Sample solution* W_S = weight of methanol in the *Standard solution* (g) r_S = peak area of methanol from the *Standard solution* W_U = weight of Sucralose to prepare the *Sample solution* (g)

▲ (NF 1-Dec-2023)

Acceptance criteria: NMT 0.1%**• RELATED COMPOUNDS****Adsorbent:** 0.20-mm layer of octadecylsilanized chromatographic silica gel. The thin-layer chromatographic plate also has a preadsorbent zone.**Detection reagent:** [Sulfuric acid](#) in [methanol](#) (3 in 20)**Standard solution A:** 10.0 mg/mL of [USP Sucralose RS](#) in [methanol](#)**Standard solution B:** 0.5 mL of *Standard solution A* diluted with [methanol](#) to 10.0 mL**Sample solution:** 100.0 mg/mL of Sucralose in [methanol](#)**Developing solvent system:** [Acetonitrile](#) and [sodium chloride](#) solution (1 in 20) (3:7)**Application volume:** 5 µL**Analysis****Samples:** *Standard solution A*, *Standard solution B*, and *Sample solution*Proceed as directed under [Chromatography \(621\)](#), [Thin-Layer Chromatography](#). Spray the plate with *Detection reagent*. Heat the plate for 10 min at 125°.**Acceptance criteria:** The R_F value of the principal spot from the *Sample solution* corresponds to that obtained from *Standard solution A*, and the color of any other single spot from the *Sample solution* is not more intense than that of the principal spot from *Standard solution B* (0.5%).**Change to read:****• LIMIT OF HYDROLYSIS PRODUCTS**

[NOTE—This test does not require a developing solvent.]

Adsorbent: 0.25-mm layer of chromatographic silica gel**Spray reagent:** 12.3 mg/mL of [p-anisidine](#) and 16.6 mg/mL of [phthalic acid](#) in [methanol](#). Store the solution in the dark and refrigerate to prevent discoloration. Discard if the solution becomes discolored. [CAUTION—*p*-Anisidine is toxic if inhaled or if absorbed through the skin.]**Standard solution A:** 100 mg/mL of [mannitol](#)**Standard solution B:** 0.4 mg/mL of fructose and 100 mg/mL of [mannitol](#)**Sample solution:** 250 mg/mL of Sucralose in [methanol](#)**Application volume:** 5-µL portions separately applied in 1-µL increments, allowing the plate to dry between applications**Analysis****Samples:** ▲ *Standard solution A*, *Standard solution B*, ▲ (NF 1-Dec-2023) and *Sample solution*Proceed as directed under [Chromatography \(621\)](#), [Thin-Layer Chromatography](#). Spray the plate with *Spray reagent*, and heat the plate at $100 \pm 2^\circ$ for 15 min. If the spot from *Standard solution A* has darkened, repeat the test, heating for a shorter period of time. Immediately after heating, view the plate against a dark background.**Acceptance criteria:** The color of the spot from the *Sample solution* is not more intense than that from *Standard solution B* (0.1%).**SPECIFIC TESTS****Change to read:****• OPTICAL ROTATION (781S), Procedures, Specific Rotation****Sample solution:** 10 mg/mL of Sucralose▲, calculated on the anhydrous basis▲ (NF 1-Dec-2023)

Acceptance criteria: +84.0° to +87.5° at 20°

- [WATER DETERMINATION \(921\), Method I](#): NMT 2.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, in a cool, dry place, at a temperature not exceeding 21°.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Sucralose RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SUCRALOSE	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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