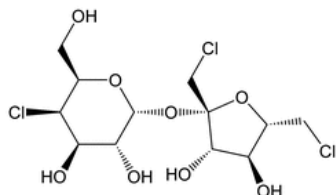


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Sucralose



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