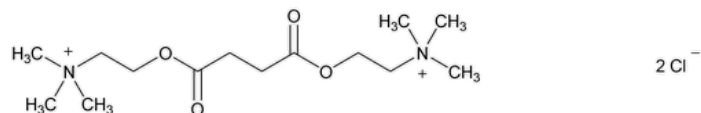


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Succinylcholine Chloride



$C_{14}H_{30}Cl_2N_2O_4$ (anhydrous) 361.31

$C_{14}H_{30}Cl_2N_2O_4 \cdot 2H_2O$ 397.34

Ethanaminium, 2,2'-[(1,4-dioxo-1,4-butanediyl)bis(oxy)]bis[N,N,N-trimethyl]-, dichloride;

Choline chloride succinate (2:1) CAS RN®: 71-27-2; UNII: I9L0DDD30I.

Dihydrate CAS RN®: 6101-15-1; UNII: 8L0S1G435E.

DEFINITION

Succinylcholine Chloride contains NLT 96.0% and NMT 102.0% of succinylcholine chloride ($C_{14}H_{30}Cl_2N_2O_4$), calculated on the anhydrous basis.

[CAUTION—Succinylcholine chloride is a neuromuscular blocking agent. Great care should be taken when handling to avoid inhalation of dust or contact with skin.]

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride:** Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Prepare a 1-in-10 solution of 1 N aqueous [tetramethylammonium chloride](#) in [methanol](#). Adjust with [hydrochloric acid](#) to a pH of about 3.0.

Standard solution: 8.8 mg/mL of [USP Succinylcholine Chloride RS](#) prepared as follows. Transfer a suitable amount of [USP Succinylcholine Chloride RS](#) to a suitable volumetric flask and dissolve in 40% of the total volume of [water](#). Dilute with *Mobile phase* to volume while mixing.

Sample solution: 8.8 mg/mL of Succinylcholine Chloride prepared as follows. Transfer a suitable amount of Succinylcholine Chloride to a suitable volumetric flask and dissolve in 40% of the total volume of [water](#). Dilute with *Mobile phase* to volume while mixing.

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Column: 4-mm × 25-cm; 10-μm packing [L3](#)

Flow rate: 0.75 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of succinylcholine chloride ($C_{14}H_{30}Cl_2N_2O_4$) in the portion of Succinylcholine Chloride taken:

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

r_U = peak response of succinylcholine chloride from the *Sample solution*

r_S = peak response of succinylcholine chloride from the *Standard solution*

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

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

Acceptance criteria: 96.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• ORGANIC IMPURITIES

Buffer: 3.85 g/L of [anhydrous sodium 1-pentanesulfonate](#), 2.9 g/L of [sodium chloride](#), and 1% (v/v) 1 N [sulfuric acid](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (5:95)

System suitability solution: 0.5 mg/mL each of [USP Citric Acid RS](#) and [USP Succinic Acid RS](#) in *Mobile phase*

Standard solution: 0.05 mg/mL of [USP Succinylmonocholine Chloride RS](#) in *Mobile phase*

Sample solution: 10 mg/mL of Succinylcholine Chloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Autosampler temperature: 4°

Flow rate: 1 mL/min

Injection volume: 50 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.9 between the citric acid and succinic acid peaks, *System suitability solution*

Relative standard deviation: NMT 3.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Succinylcholine Chloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak area of each impurity from the *Sample solution*

r_S = peak area of succinylmonocholine chloride from the *Standard solution*

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

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

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Edetate disodium ^a	0.18	—	—
Succinic acid	0.22	1.6	0.1
Unidentified impurity 1 ^b	0.32	1.0	0.4

