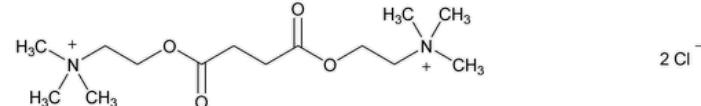


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## Succinylcholine Chloride



$C_{14}H_{30}Cl_2N_2O_4$  (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 <sup>a</sup>	0.18	—	—
Succinic acid	0.22	1.6	0.1
Unidentified impurity 1 <sup>b</sup>	0.32	1.0	0.4

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Unidentified impurity 2 <sup>b</sup>	0.32	1.0	
Succinylmonocholine	0.49	1.0	0.4
Succinylcholine	1.0	—	—
Any unspecified impurity	—	1.0	0.2
Total impurities <sup>b,c</sup>	—	—	1.5

<sup>a</sup> Included for identification purposes only. Begin integration after this peak, if present.

<sup>b</sup> May occur as a doublet. Acceptance criteria is for the sum of both peaks.

<sup>c</sup> Total impurities include the sum of the results in the tests for *Organic Impurities* and *Limit of Choline*.

• **LIMIT OF CHOLINE**

**Solution A:** 0.62 g/L of [methanesulfonic acid](#)

**Solution B:** 4.8 g/L of [methanesulfonic acid](#)

**Mobile phase:** See [Table 2](#). Pre-equilibrate the instrument for NLT 3 min before each injection. [NOTE—Alternatively, the *Mobile phase* can be generated electrolytically using an automatic eluant generator.]

**Table 2**

Time (min)	Solution A (%)	Solution B (%)
0	100	0
14	100	0
15	0	100
33	0	100
34	100	0
40	100	0

**System suitability solution:** 10 µg/mL of [USP Choline Chloride RS](#) and 5 µg/mL of [USP Potassium Chloride RS](#)

**Standard solution:** 8 µg/mL of [USP Choline Chloride RS](#)

**Sample solution:** 2 mg/mL of Succinylcholine Chloride. Store at 4° immediately following preparation.

**Chromatographic system**

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

**Mode:** LC

**Detector:** Conductivity with suppression

**Cell temperature:** 35°

**Columns**

**Guard:** 2-mm × 5-cm; packing [L98](#)

**Analytical:** 2-mm × 25-cm; packing [L97](#)

**Temperatures**

**Autosampler:** 4°

**Column:** 35°

**Flow rate:** 0.25 mL/min

**Injection volume:** 5 µL

**System suitability**

**Sample:** System suitability solution

[NOTE—The relative retention times for potassium and choline are 0.6 and 1.0, respectively.]

**Suitability requirements****Resolution:** NLT 5.0 between the choline and potassium peaks**Relative standard deviation:** NMT 3.0% for choline**Analysis****Samples:** Standard solution and Sample solution

Calculate the percentage of choline in the portion of Succinylcholine Chloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

 $r_U$  = peak response of choline from the Sample solution $r_S$  = peak response of choline from the Standard solution $C_S$  = concentration of [USP Choline Chloride RS](#) in the Standard solution (mg/mL) $C_U$  = concentration of Succinylcholine Chloride in the Sample solution (mg/mL) $M_{r1}$  = molecular weight of choline, 104.17 $M_{r2}$  = molecular weight of choline chloride, 139.62**Acceptance criteria:** NMT 0.3%**SPECIFIC TESTS**

- [WATER DETERMINATION \(921\), Method I](#): NMT 10.0%

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers. Store at controlled room temperature.

**Change to read:**

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Choline Chloride RS](#)[USP Citric Acid RS](#)[USP Potassium Chloride RS](#)[USP Succinic Acid RS](#)[USP Succinylcholine Chloride RS](#)[USP Succinylmonocholine Chloride RS](#)

Ethanaminium, 2-(▲3-▲ (ERR 1-Jan-2022) carboxy-1-oxopropoxy)-N,N,N-trimethyl-, chloride;

▲Also known as 2-[(3-Carboxypropanoyl)oxy]-N,N,N-trimethylethan-1-aminium chloride.▲ (ERR 1-Jan-2022)

 $C_9H_{18}ClNO_4$  239.70**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SUCCINYLCHOLINE CHLORIDE	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM52020 Small Molecules 5

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