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Succinylcholine Chloride Injection

DEFINITION

Succinylcholine Chloride Injection is a sterile solution of Succinylcholine Chloride in a suitable aqueous vehicle. It contains NLT 90.0% and NMT 110.0% of the labeled amount of anhydrous succinylcholine chloride ($C_{14}H_{30}Cl_2N_2O_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** Thin-Layer Chromatographic Identification Test ⟨201⟩

Standard solution: 1 mg/mL of USP Succinylcholine Chloride RS in water

Sample solution: Nominally 1 mg/mL of succinylcholine chloride from Injection in water

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 1 µL

Developing solvent system: Acetone and 1 N hydrochloric acid (1:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. To locate the spots, heat the plate at 105° for 5 min, cool, and spray with potassium bismuth iodide TS, then heat again at 105° for 5 min.

Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

[Note—Because the *Mobile phase* used in this procedure has a fairly high concentration of chloride ion and a low pH, it is advisable to rinse the entire system with water following use of this *Mobile phase*.]

Mobile phase: Prepare a solution (1 in 10) of 1 N tetramethylammonium chloride in methanol. Pass this solution through a 0.45-µm membrane filter, and adjust with hydrochloric acid to a pH of 3.0.

Standard solution: 8.8 mg/mL of USP Succinylcholine Chloride RS prepared as follows. Transfer 88 mg of USP Succinylcholine Chloride RS to a 10-mL volumetric flask and add a volume of water corresponding to the solvent composition of the *Sample solution*. Dilute with *Mobile phase* to volume. Prepare the *Standard solution* concurrently with the *Sample solution*.

Sample solution: Nominally 8.0 mg/mL of succinylcholine chloride prepared as follows. Transfer a volume of Injection equivalent to 80 mg of anhydrous succinylcholine chloride to a 10-mL volumetric flask and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 214 nm

Column: 4-mm × 25-cm; 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 the labeled amount of anhydrous succinylcholine chloride ($C_{14}H_{30}Cl_2N_2O_4$) in the portion of Injection 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 Succinylcholine Chloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of succinylcholine chloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 2.0 USP Endotoxin Units/mg of succinylcholine chloride
- **pH ⟨791⟩:** 3.0–4.5
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type II glass, in a refrigerator.
- **Labeling:** Label it to indicate, as its expiration date, the month and year NMT 2 years from the month during which the Injection was last assayed and released by the manufacturer.
- **USP Reference Standards ⟨11⟩**
  USP Succinylcholine Chloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SUCCINYLCHOLINE CHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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