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Sodium Thiosulfate Injection

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-sodium-thiosulfate-inj-20230331.

DEFINITION

Sodium Thiosulfate Injection is a sterile solution of Sodium Thiosulfate in freshly boiled Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of sodium thiosulfate ($\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$).

IDENTIFICATION

• A.

Sample solution: Equivalent to 0.1 g/mL of sodium thiosulfate in [water](#)

Analysis: Add a few drops of [iodine TS](#).

Acceptance criteria: The color is discharged.

• B. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Sodium](#)

Sample solution: Equivalent to 0.1 g/mL of sodium thiosulfate in [water](#)

Acceptance criteria: Meets the requirements

• C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Thiosulfate](#)

Sample solution: Equivalent to 0.1 g/mL of sodium thiosulfate in [water](#)

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Sample solution: Equivalent to 1 g of sodium thiosulfate from Injection. Adjust with a suitable solution of dilute [hydrochloric acid](#) or dilute [sodium hydroxide](#) to a pH of 6.2–6.7, and dilute with [water](#) to about 20 mL.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [0.1 N iodine VS](#)

Endpoint detection: Visual

Analysis: Titrate the *Sample solution* with *Titrant*, adding 3 mL of [starch TS](#) as the endpoint is approached. Each mL of *Titrant* is equivalent to 24.82 mg of sodium thiosulfate ($\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$).

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• [BACTERIAL ENDOTOXINS TEST \(85\)](#): NMT 0.03 USP Endotoxin Units/mg of sodium thiosulfate

• [pH \(791\)](#): 6.0–9.5

• **OTHER REQUIREMENTS:** Meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

Change to read:

• **PACKAGING AND STORAGE:** Preserve in single-dose containers▲, preferably▲ (RB 1-Apr-2023) of Type I glass.

Topic/Question	Contact	Expert Committee
SODIUM THIOSULFATE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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