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Stannous Chloride

$SnCl_2 \cdot 2H_2O$ 225.65

Tin chloride ($SnCl_2$) dihydrate CAS RN®: 10025-69-1.

DEFINITION

Stannous Chloride contains NLT 98.0% and NMT 102.0% of stannous chloride ($SnCl_2 \cdot 2H_2O$).

IDENTIFICATION

- **A.**

Sample solution: To 0.40 g of Stannous Chloride add 1 mL of dilute hydrochloric acid solution (236 mL/L of hydrochloric acid), and dilute with water to 20 mL. [Note—Keep a portion for the *Limit of Sulfate* test.]

Analysis: To 1 mL of the *Sample solution* add a mixture of 5 mL of water and 0.05 mL of mercuric chloride TS.

Acceptance criteria: A blackish-gray precipitate forms.

- **B.**

Sample: 1.0 g

Analysis 1: Dissolve the *Sample* in 3.0 mL of water. Add 0.5 mL of dilute sodium hydroxide solution (85 mg/mL of sodium hydroxide) to the cloudy solution.

Acceptance criteria 1: A yellowish, flocculent precipitate is formed.

Analysis 2: Add 6.5 mL of water to the solution resulting from *Analysis 1*. To 1.0 mL of the previously shaken suspension add 1.0 mL of sodium hydroxide solution (420 mg/mL of sodium hydroxide).

Acceptance criteria 2: The precipitate dissolves, and the resulting solution is clear and colorless.

- **C.** **Identification Tests—General, *Chloride* ⟨191⟩**

Sample solution: Dissolve 10 mg of Stannous Chloride in 2 mL of 20% nitric acid.

Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

Sample: 0.1 g of Stannous Chloride

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.1 N iodine VS

Blank: 50 mL of water

Endpoint detection: Colorimetric

Analysis: Dissolve the *Sample* in 50 mL of water freed from oxygen by purging with carbon dioxide or nitrogen for 15 min prior to the addition. Add 1.5 mL of 0.8 N hydrochloric acid, 5 g of potassium sodium tartrate, 10 g of sodium bicarbonate, and 1 mL of starch TS. Titrate the resulting solution immediately with *Titrant*. Perform a blank determination.

Calculate the percentage of stannous chloride ($SnCl_2 \cdot 2H_2O$) in the *Sample*:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* consumed by the *Sample* (mL)

V_B = *Titrant* consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 112.8 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• **Limit of Sulfate**

Acetic acid solution: Dilute 30 mL of glacial acetic acid with water to 100 mL.

30% Alcohol: Dilute 30 mL of alcohol with water to 100 mL.

Potassium sulfate solution 1: 1.8 mg/mL of potassium sulfate in *30% Alcohol*. Immediately before use, dilute with *30% Alcohol* to obtain a solution having a known concentration of about 18 µg/mL.

Potassium sulfate solution 2: 1.8 mg/mL of potassium sulfate in water. Immediately before use, dilute with water to obtain a solution having a known concentration of about 18 µg/mL.

Standard solution: Mix 3 mL of barium chloride solution (250 mg/mL) and 4.5 mL of *Potassium sulfate solution 1*. Shake, and let stand for 1 min. To 2.5 mL of this solution add 15 mL of *Potassium sulfate solution 2* and 0.5 mL of *Acetic acid solution*. Allow to stand for 5 min.

Sample solution: Use 15 mL of the solution prepared in *Identification* test *A*.

Analysis: Mix 3 mL of barium chloride solution (250 mg/mL) and 4.5 mL of *Potassium sulfate solution 1*. Shake, and let stand for 1 min. To 2.5 mL of this solution add the *Sample solution* and 0.5 mL of *Acetic acid solution*. Allow to stand for 5 min.

Acceptance criteria: Any opalescence in the *Sample solution* is not more intense than that in the *Standard solution* (500 ppm).

Change to read:

• **Limit of Iron**

Standard iron solution: Prepare as directed in ▲*Iron ⟨241⟩, Procedures, Procedure 1*▲ (CN 1-Jun-2023) ·

Standard solution: Immediately before use, dilute 1 mL of *Standard iron solution* with water to 10 mL. This solution contains the equivalent of 1 µg/mL of iron.

Sample solution: Dilute 5 mL of the *Sample solution*, prepared as directed in *Substances Not Precipitated by Thioacetamide*, with water to 10 mL.

Analysis: To 10 mL each of the *Standard solution* and the *Sample solution* add 2 mL of dilute citric acid (200 mg/mL) and 0.1 mL of thioglycolic acid, and mix. Make alkaline with a dilute ammonia solution (620 mL/L of ammonium hydroxide). Dilute with water to 20 mL. Allow the treated *Standard solution* and the treated *Sample solution* to stand for 5 min.

Acceptance criteria: Any pink color in the *Sample solution* is not more intense than that in the *Standard solution* (100 ppm).

• **Limit of Lead**

Dilute thioacetamide solution: [Note—Prepare immediately before use.] To 0.2 mL of thioacetamide TS add 1 mL of a mixture of 5 mL of water, 15 mL of 1 N sodium hydroxide, and 20 mL of 85% glycerin. Heat in a water bath for 20 s.

Standard solution: On the day of use, mix 1.0 mL of standard lead solution TS, 6 mL of water, 3 mL of sodium hydroxide solution (420 mg/mL of sodium hydroxide), and 0.5 mL of *Dilute thioacetamide solution.*

Sample solution: Dissolve 1.0 g of Stannous Chloride in 2 mL of a mixture of nitric acid and hydrochloric acid (1:3). Heat the solution on a water bath until nitrous vapor is no longer evolved. Dissolve the residue in water, and dilute with water to 25 mL. To 5 mL of this solution add 3 mL of sodium hydroxide solution (420 mg/mL of sodium hydroxide) and 2 mL of water. Heat until a clear solution is obtained, and cool. Add 0.5 mL of *Dilute thioacetamide solution*, and allow to stand for 2 min.

Analysis: Compare the *Standard solution* and the *Sample solution*.

Acceptance criteria: Any color in the *Sample solution* is not more intense than that in the *Standard solution* (50 µg/g).

SPECIFIC TESTS

• **Appearance of Solution**

Standard stock solution: Pipet 30.0 mL of ferric chloride CS, 30.0 mL of cobaltous chloride CS, and 24.0 mL of cupric sulfate CS into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume.

Standard solution: Dilute 1.0 mL of the *Standard stock solution* with 1% (w/v) hydrochloric acid to 100 mL.

Sample solution: Dissolve 10.0 g of Stannous Chloride in dilute hydrochloric acid solution, and dilute with dilute hydrochloric acid solution to 20 mL.

Acceptance criteria: The *Sample solution* is clear and colorless, or if not, not more intensely colored than the *Standard solution*.

• **Substances Not Precipitated by Thioacetamide**

Sample solution: Dissolve 1.0 g of Stannous Chloride in dilute hydrochloric acid solution, and dilute with the same acid to 30 mL. Heat to boiling. Add 30 mL of thioacetamide TS, and boil for 15 min to produce *Solution A*. Filter 5 mL of *Solution A*, and heat the filtrate to boiling. Add 5 mL of thioacetamide TS, and boil for 15 min. If a precipitate is formed, add the remainder of *Solution A* to the mixture to produce *Solution A1*. Add 10 mL of thioacetamide TS, and boil. Repeat the series of operations from "Filter 5 mL" until a precipitate is no longer formed on addition of thioacetamide TS to the filtrate obtained from the 5 mL of *Solution A* (*Solution A1*, *Solution A2*, and so on, respectively). If no precipitate is formed, or if no more precipitate is formed, combine the solution obtained with the remainder of *Solution A* (*Solution A1*, *Solution A2*, and so on, respectively), filter, and wash the precipitate with 10 mL of water. Heat the filtrate until the resulting vapor no longer turns a moistened piece of lead acetate test paper blackish-gray. Allow to cool, and dilute with water to 50 mL. [Note—Keep a portion for the *Limit of Iron* test.]

Analysis: Evaporate 25 mL of the *Sample solution* to dryness, and ignite at 600°.

Acceptance criteria: The residue weighs NMT 1 mg (0.2%).

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

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

Topic/Question	Contact	Expert Committee
STANNOUS CHLORIDE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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