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Stannous Fluoride

Change to read:

SnF_2 156.71

▲Tin (II) fluoride;

Difluoro- λ^2 -stannane▲ (USP 1-Aug-2022) CAS RN®: 7783-47-3; UNII: 3FTR44B32Q.

Change to read:

DEFINITION

Stannous Fluoride contains NLT 71.2% of stannous tin ($\text{Sn}^{\text{▲}2+}$ ▲ (USP 1-Aug-2022)), and NLT 22.3% and NMT 25.5% of fluoride ($\text{F}^{\text{▲}-}$ ▲ (USP 1-Aug-2022)), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲The retention time of the fluoride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 2: Fluoride*.▲ (USP 1-Aug-2022)
- **B.**
Sample solution: 10 mg/mL of Stannous Fluoride in [water](#)
Analysis: On a spot plate, mix 2 drops of the *Sample solution* with 2 drops of [silver nitrate TS](#).
Acceptance criteria: A brown-black precipitate is formed.
- **C.**
Sample solution: 10 mg/mL of Stannous Fluoride in [water](#)
Analysis: Add 1 drop of the *Sample solution* to 2 drops of [mercuric chloride TS](#).
Acceptance criteria: A white, silky precipitate is formed. On further addition of the *Sample solution*, a brown-black precipitate is formed.

ASSAY

Change to read:

- **PROCEDURE 1: STANNOUS ▲TIN▲** (USP 1-Aug-2022)

Solution A: 5 mg/mL of [sodium hydroxide](#) and 50 mg/mL of [potassium iodide](#) in oxygen-free [water](#)

Potassium iodide–iodate solution: 0.1 N potassium iodide–iodate solution prepared as follows. In a 1000-mL volumetric flask, dissolve 3.567 g of [potassium iodate](#), previously dried at 110° to constant weight, in 200 mL of *Solution A*, and dilute with oxygen-free [water](#) to volume. Standardize this solution by titrating a solution prepared from an accurately weighed quantity of [tin](#) (Sn) and [hydrochloric acid](#). Each milliliter of 0.1 N potassium iodide–iodate solution is equivalent to 5.935 mg of tin (Sn).

Sample: 250 mg of Stannous Fluoride

Titrimetric system

▲(See [Titrimetry \(541\)](#).)▲ (USP 1-Aug-2022)

Mode: Direct titration

Titrant: *Potassium iodide–iodate solution*

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 500-mL conical flask, and add 300 mL of hot, recently boiled 3 N [hydrochloric acid](#). While passing a stream of an oxygen-free inert gas over the surface of the liquid, swirl the flask to dissolve the *Sample*, and cool to room temperature. Add 5 mL of [potassium iodide TS](#), and titrate in an inert atmosphere with *Titrant*, adding 3 mL of [starch TS](#) as the endpoint is approached.

▲Calculate the percentage of stannous tin (Sn^{2+}) in the portion of Stannous Fluoride taken:

$$\text{Result} = V_s \times N \times F \times (1/W) \times 100$$

V_s = volume of *Titrant* consumed by the *Sample* (mL)

N = actual *Titrant* concentration, in normality (mEq/mL)

F = equivalency factor of stannous tin, 59.35 mg/mEq

W = weight of the *Sample* taken (mg)▲ (USP 1-Aug-2022)

Acceptance criteria: NLT 71.2% on the dried basis

Change to read:

• **PROCEDURE 2: FLUORIDE**

▲[NOTE—Store all solutions in plastic containers. It is recommended to use plastic HPLC vials. Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]

Mobile phase: 15 mM [potassium hydroxide](#) in [water](#). [NOTE—*Mobile phase* can be generated electrolytically using an automatic eluant generator.]

System suitability solution: 2.0 µg/mL of [USP Sodium Fluoride RS](#) and 1.0 µg/mL of [USP Sodium Acetate RS](#) in [water](#)

Standard solution: 2.0 µg/mL of [USP Sodium Fluoride RS](#) in [water](#)

Sample solution: 3.7 µg/mL of Stannous Fluoride in [water](#)

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4.0-mm × 5-cm; 13-µm packing [L120](#). [NOTE—Alternatively, a 4.0-mm × 0.5-cm column that contains 4.6-µm packing [L91](#) may be used.]

Analytical: 4.0-mm × 25-cm; 7.5-µm packing [L113](#). [NOTE—Alternatively, a 4.0-mm × 25-cm column that contains 4.6-µm packing [L91](#) may be used.]

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Run time: NLT 6 times the retention time of fluoride

System suitability

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

[NOTE—The relative retention times for the fluoride and acetate ions are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the fluoride and acetate ions, *System suitability solution*

Tailing factor: NMT 2.0 for the fluoride ion, *Standard solution*

Relative standard deviation: NMT 1.0% for the fluoride ion, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fluoride (F^-) in the portion of Stannous Fluoride taken:

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

r_U = peak response of the fluoride ion from the *Sample solution*

r_S = peak response of the fluoride ion from the *Standard solution*

C_S = concentration of [USP Sodium Fluoride RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Stannous Fluoride in the *Sample solution* (µg/mL)

A_r = atomic weight of fluoride, 19.00

M_r = molecular weight of sodium fluoride, 41.99▲ (USP 1-Aug-2022)

Acceptance criteria: 22.3%–25.5% on the dried basis

IMPURITIES

Change to read: