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Sodium Fluoride Tablets

DEFINITION

Sodium Fluoride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of sodium fluoride (NaF).

IDENTIFICATION

• **A.** Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*

Sample solution: Disperse 20 finely powdered Tablets in 25 mL of water, shake, and filter. Use the filtrate.

Acceptance criteria: The filtrate meets the requirements.

Change to read:

• **B.** ▲The retention time of the fluoride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲

(USP 1-May-2020)

ASSAY

Change to read:

• **Procedure**

▲[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.]

Solution A: 100 mM of potassium hydroxide in water

Solution B: Water

Mobile phase: See *Table 1*. Alternatively, *Mobile phase* can be generated electrolytically using an automatic eluant generator.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	15	85
7.0	15	85
8.0	80	20
15.0	80	20
15.1	15	85
25.0	15	85

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 stock solution: Nominally 20 µg/mL of sodium fluoride prepared as follows. Finely powder NLT 20 Tablets and transfer an appropriate portion of the powder to a suitable volumetric flask. Add about 40% of the final volume of water. Shake for about 30 min and dilute with water to volume.

Sample solution: Nominally 2.0 µg/mL of sodium fluoride in water from the *Sample stock solution* prepared as follows. Transfer an appropriate amount of well-mixed *Sample stock solution* to a suitable volumetric flask. Dilute with water to volume and mix well. Centrifuge a portion of the solution and use the clear supernatant. [Note—Centrifuging at a speed of 8000 rpm for 10 min may be suitable.]

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4.0-mm × 0.5-cm; 4.6-µm packing L91

Analytical: 4.0-mm × 25-cm; 4.6-µm packing L91

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for fluoride and acetate ions are 1.0 and 1.3, respectively.]

Suitability requirements

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

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium fluoride (NaF) in the portion of Tablets taken:

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

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

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

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

C_U = nominal concentration of sodium fluoride in the *Sample solution* (µg/mL)

▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **DISINTEGRATION ⟨701⟩:** NMT 15 min

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

Change to read:

• **PACKAGING AND STORAGE:** Preserve in tight containers. ▲Store at controlled room temperature.▲ (USP 1-May-2020)

• **LABELING:** Label the Tablets in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion. Tablets that are to be chewed may be labeled as Sodium Fluoride Chewable Tablets.

Change to read:

• **USP REFERENCE STANDARDS ⟨11⟩**

▲USP Sodium Acetate RS▲ (USP 1-May-2020)

USP Sodium Fluoride RS

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

Topic/Question	Contact	Expert Committee
SODIUM FLUORIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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