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Sodium Fluoride

NaF 41.99

Sodium fluoride CAS RN®: 7681-49-4; UNII: 8ZYQ1474W7.

DEFINITION
Sodium Fluoride contains NLT 98.0% and NMT 102.0% of sodium fluoride (NaF), calculated on the dried basis.

IDENTIFICATION
Change to read:

• **A. Fluoride:** ▲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-Aug-2021)

Change to read:

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

Sample solution: ▲40 mg/mL in water▲ (USP 1-Aug-2021)

Acceptance criteria: Meets the requirements

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.]

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: 2.0 µg/mL of Sodium 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 0.73% for the fluoride ion, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium fluoride (NaF) in the portion of Sodium Fluoride taken:

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

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 Sodium Fluoride in the *Sample solution* (µg/mL)

▲ (USP 1-Aug-2021)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

Change to read:

• **Chloride**

▲[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 and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 1.0 mg/mL of USP Sodium Fluoride RS and 1.0 µg/mL of USP Sodium Chloride RS in water

Standard solution: 0.2 µg/mL of USP Sodium Chloride RS in water

Sample solution: 1.0 mg/mL of Sodium Fluoride in water

System suitability

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

[Note—The relative retention times for the fluoride and chloride ions are 1.0 and 1.6, respectively.]

Suitability requirements

Resolution: NLT 4 between the fluoride and chloride ions, *System suitability solution*

Relative standard deviation: NMT 5.0% for the chloride ion, *Standard solution*

Signal-to-noise ratio: NLT 20, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of chloride ion in the portion of Sodium 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 chloride ion from the *Sample solution*

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

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

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

A_r = atomic weight of chloride, 35.453

M_r = molecular weight of sodium chloride, 58.44

Acceptance criteria: NMT 0.012%▲ (USP 1-Aug-2021)

SPECIFIC TESTS

• **Acidity or Alkalinity**

Sample: 2.0 g

Analysis: Dissolve the *Sample* in 40 mL of water in a platinum dish. Add 10 mL of a saturated solution of potassium nitrate, cool the solution to 0°, and add 3 drops of phenolphthalein TS.

Acceptance criteria: If no color appears, a pink color persisting for 15 s is produced by NMT 2.0 mL of 0.10 N sodium hydroxide. If the solution is colored pink by the addition of phenolphthalein TS, it is rendered colorless by NMT 0.50 mL of 0.10 N sulfuric acid. [Note—Save the neutralized solution for the test for *Fluosilicate*.]

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 150° for 4 h.

Acceptance criteria: NMT 1.0%

• **Fluosilicate**

Analysis: After the solution from the test for *Acidity or Alkalinity* has been neutralized, heat to boiling, and titrate while hot with 0.10 N sodium hydroxide until a permanent pink color is obtained.

Acceptance criteria: NMT 1.5 mL of 0.10 N sodium hydroxide is required.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

Add the following:

▲• **USP REFERENCE STANDARDS ⟨11⟩**

USP Sodium Acetate RS
USP Sodium Chloride RS
USP Sodium Fluoride RS▲ (USP 1-Aug-2021)

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

Topic/Question	Contact	Expert Committee
SODIUM FLUORIDE	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

Most Recently Appeared In:
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