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Sodium Fluoride Oral Solution

DEFINITION

Sodium Fluoride Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium fluoride (NaF).

IDENTIFICATION

- **A.** The retention time of the fluoride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*

Sample solution: 10 mg/mL of sodium in Oral Solution. If necessary, reduce the volume of a portion of Oral Solution by heating on a steam bath.

Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

[Note—Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]

Mobile phase: 150 mg/L of anhydrous sodium carbonate and 1.0 mL/L of 1 N sodium hydroxide in water. Pass through a suitable filter of 0.45-µm pore size.

System suitability solution: 1.0 µg/mL of USP Sodium Fluoride RS and 0.5 µg/mL of USP Sodium Chloride RS in water

Standard solution: 1.1 µg/mL of USP Sodium Fluoride RS in water

Sample solution: Nominally 1.1 µg/mL of sodium fluoride from a portion of Oral Solution in water

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4.0-mm × 5-cm; 10-µm packing L46

Analytical: 4.0-mm × 25-cm; 10-µm packing L46

Flow rate: 1.0 mL/min

Injection volume: 20 µL

[Note—It is recommended to use polymethylpentene HPLC vials.]

Run time: NLT 2 times the retention time of the fluoride peak

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for fluoride and chloride ions are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 1.5 between fluoride and chloride ions

Tailing factor: NMT 2.0 for fluoride ion

Relative standard deviation: NMT 2.0% for fluoride ion

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

r_S = peak response of fluoride 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)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers; use plastic containers for Oral Solution having a pH below 7.5.
- **Labeling:** Label the Oral Solution in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion.
- **USP Reference Standards** ⟨11⟩

  USP Sodium Chloride RS

  USP Sodium Fluoride RS

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

Topic/Question	Contact	Expert Committee
SODIUM FLUORIDE ORAL SOLUTION	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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