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Sodium Fluoride and Acidulated Phosphate Topical Solution

DEFINITION

Sodium Fluoride and Acidulated Phosphate Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of fluoride ion.

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*.▲1S *(USP41)*

Change to read:

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

▲**Sample:** A portion of Topical Solution

[Note—If the *Sample* contains hydrogen peroxide, use of a platinum-coated disc to neutralize hydrogen peroxide is recommended prior to performing the test.]

▲1S *(USP41)*

Acceptance criteria: Meets the requirements

ASSAY

Delete the following:

▲• **Procedure 1**

[Note—Store all solutions, except *Buffer*, in plastic containers.]

Buffer: Dissolve 57 mL of glacial acetic acid, 58 g of sodium chloride, and 4 g of (1,2-cyclohexylenedinitrilo)tetraacetic acid in 500 mL of water. Adjust with 5 N sodium hydroxide to a pH of 5.25 ± 0.25, and dilute with water to 1000 mL.

Standard solution A: 420 µg/mL of USP Sodium Fluoride RS in water, equivalent to 190 µg/mL of fluoride ion (10^{-2} M)

Standard solution B: 19 µg/mL of fluoride ion (10^{-3} M) in water, from *Standard solution A*

Standard solution C: 1.9 µg/mL of fluoride ion (10^{-4} M) in water, from *Standard solution B*

Sample solution: Nominally 20 µg/mL of fluoride ion from Topical Solution in water

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*

Pipet 20 mL of *Standard solution A*, *Standard solution B*, *Standard solution C* and *Sample solution* into separate plastic beakers, each containing a plastic-coated stirring bar. Pipet 20 mL of *Buffer* into each beaker. Concomitantly measure the potentials (see *pH* ⟨791⟩), in mV, of each solution with a pH meter capable of a minimum reproducibility of ± 0.2 mV and equipped with a fluoride-specific ion-indicating electrode and a suitable reference electrode.

[Note—When taking measurements, immerse the electrodes in the solution, stir on a magnetic stirrer having an insulated top until equilibrium is attained (1–2 min), and record the potential. Rinse and dry the electrodes between measurements, taking care to avoid damaging the crystal of the specific-ion electrode.]

Plot the logarithms of the fluoride-ion concentrations, in µg/mL, of *Standard solution A*, *Standard solution B*, and *Standard solution C* versus potential, in mV. From the measured potential of the *Sample solution* and the standard response line, determine the concentration, *C*, in µg/mL, of fluoride ion in the *Sample solution*.

Calculate the percentage of the labeled amount of fluoride ion in the Topical Solution taken:

$$\text{Result} = (C/C_U) \times 100$$

C = concentration of fluoride in the *Sample solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0% ▲1S *(USP41)*

Change to read:

• **Procedure**▲ ▲1S *(USP41)*

[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:** 1.1 µg/mL of USP Sodium Fluoride RS and 0.5 µg/mL of USP Sodium Chloride RS in water▲1S *(USP41)*

Standard solution: ▲▲1S *(USP41)* 1.1 µg/mL of USP Sodium Fluoride RS in water. Pass through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally ▲0.5 µg/mL of fluoride ion▲ (ERR 1-Aug-2018) from a portion of Topical Solution in water. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4.6-mm × 5-cm; ▲7-µm packing▲1S *(USP41)* L46

Analytical: 4.6-mm × 25-cm; ▲7-µm packing▲1S *(USP41)* L46

Flow rate: 1.0 mL/min

Injection volume: 20 µL

[Note—Use of polymethylpentene HPLC vials is recommended.]

▲**Run time:** NLT 2 times the retention time of the fluoride peak▲1S *(USP41)*

System suitability

▲**Sample:** *System suitability solution*

[Note—The relative retention times for fluoride and chloride ions are 1.0 and 1.2, respectively.]▲1S *(USP41)*

Suitability requirements

Resolution: NLT 1.5 between fluoride and chloride ions ▲▲1S *(USP41)*

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 fluoride ion in the portion of Topical Solution taken:

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

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 ▲fluoride ion▲ (ERR 1-Aug-2018) in the *Sample solution* (µg/mL)

A_r = atomic weight of fluoride, 19.00

M_r = molecular weight of sodium fluoride, 41.99

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩

Analysis: Place about 40 mL in a plastic beaker, and determine the pH using a suitable electrode system.

Acceptance criteria: 3.0–4.5

Delete the following:

▲• **Other Requirements:** It responds to the *Identification* tests under *Sodium Fluoride and Phosphoric Acid Gel*. ▲1S *(USP41)*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, plastic containers.

Change to read:

• **Labeling:** Label the Topical Solution in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion.▲▲1S *(USP41)*

Change to read:

• **USP Reference Standards** ⟨11⟩

▲ USP Sodium Chloride RS ▲1S *(USP41)*

USP Sodium Fluoride RS

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

Topic/Question	Contact	Expert Committee
SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPICAL 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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