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Sodium Fluoride and Phosphoric Acid Gel

DEFINITION

Sodium Fluoride and Phosphoric Acid Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of fluoride ion, in an aqueous medium containing a suitable viscosity-inducing agent.

IDENTIFICATION

• **A.**

Sample: A suitable quantity of Gel nominally equivalent to about 500 mg of fluoride ion

Analysis: Place the *Sample* in a platinum crucible in a well-ventilated hood, and add 15 mL of *sulfuric acid*. Cover the crucible with a piece of clear, polished glass, and heat on a steam bath for 1 h. Remove the glass cover, rinse it in water, and dry.

Acceptance criteria: The glass surface exposed to vapors from the crucible is etched.

• **B.** **Identification Tests—General⟨191⟩, *Chemical Identification Tests, Phosphate*:** Meets the requirements

ASSAY

• **Procedure**

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

Buffer solution: 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 (10^{-2} M) of fluoride ion

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

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

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

Analysis

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

Transfer 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. Transfer 20 mL of *Buffer solution* into each beaker. Concomitantly measure the potentials (see *pH ⟨791⟩*), in millivolts , 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 millivolts . 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 portion of Gel 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%

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample: About 40 mL

Analysis: Place the *Sample* in a plastic beaker, and determine the pH using a suitable electrode system.

Acceptance criteria: 3.0–4.0

- **Viscosity—Rotational Methods ⟨912⟩**

Sample: A portion of Gel

Analysis: Transfer the *Sample* to a suitable plastic container, insert the stopper securely, and allow to stand until the *Sample* is free from air bubbles. Place it in a water bath maintained at a temperature of 25 ± 0.5° until it adjusts to the temperature of the water bath (30 min or longer). Do not stir the *Sample* while it is in the bath. Remove the *Sample* from the bath, stir the *Sample* gently for 5 s, and without delay, using a rotational viscometer, determine the viscosity using the appropriate spindle to obtain a scale reading between 10% and 90% of full scale at a speed of 60 rpm or 30 rpm.

Calculate the viscosity, in centipoises, by multiplying the scale reading by the constant for the spindle and speed used.

Acceptance criteria: 7,000–20,000 centipoises

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, plastic containers.
- **Labeling:** Label Gel in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion.
- **USP Reference standards ⟨11⟩**

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 PHOSPHORIC ACID GEL	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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