Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: USP Monographs
DocId: GUID-BD6E0DE6-EC21-480E-8649-CD01C814DC8F_2_en-US
DOI: https://doi.org/10.31003/USPNF_M3947_02_01
DOI Ref: kfu3a

Sodium Fluoride Gel

DEFINITION

Sodium Fluoride Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium fluoride (NaF), in an aqueous medium containing a suitable viscosity-inducing agent. It may contain a suitable buffering agent.

[Note—This monograph is only applicable to *Preventive treatment gels* and is not applicable to *Dentifrices* as defined under 21 CFR §355.3.]

IDENTIFICATION

Change to read:

• **▲A.▲** (USP 1-May-2020)

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

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

Acceptance criteria: The surface of the glass is etched.

Add the following:

▲• 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.]

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: Nominally 2.0 µg/mL of sodium fluoride from a portion of Gel in water

Chromatographic system

(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

Run time: NLT 3 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 1.3, 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 2.0% for the fluoride ion, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium fluoride (NaF) in the portion of Gel 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 = nominal concentration of sodium fluoride in the *Sample solution* (µg/mL)

▲ (USP 1-May-2020)

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: 6.0–8.0

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight, plastic containers. ▲Store at controlled room temperature.▲ (USP 1-May-2020)

• **Labeling:** Label the Gel in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion.

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 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(4)

Current DocID: GUID-BD6E0DE6-EC21-480E-8649-CD01C814DC8F_2_en-US

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