Packaging and storage—Preserve in tight containers.

Identification—
A: It meets the requirements of the flame test for Sodium (191).
B: Add 2 mL of 15% potassium carbonate TS to 2 mL of Oral Solution, boil, and cool. Add 4 mL of potassium pyroantimonate TS: a dense precipitate is formed (presence of sodium).
C: To 2 mL of a dilution of Oral Solution (1 in 20) add 5 mL of sodium cobaltinitrite TS: a yellow precipitate is not formed immediately (absence of potassium).
D: It meets the requirements of the tests for Citrate (191), 3 to 5 drops of Oral Solution and 20 mL of the mixture of pyridine and acetic anhydride being used.

Uniformity of dosage units (905)—
For oral solution packaged in single-unit containers: meets the requirements.
Deliverable volume (698)—
For Oral Solution packaged in multiple-unit containers: meets the requirements.

pH (791): Between 4.0 and 4.4.

Sodium Fluoride

Sodium Fluoride contains not less than 98.0 percent and not more than 102.0 percent of NaF, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

Identification—
A: Place 1 g in a platinum crucible in a well-ventilated hood, and 14.61 is the equivalent, in mg, of C₆H₆O₇·H₂O, in each mL of the mixture of pyridine and acetic anhydride being used.
B: A solution (1 in 25) responds to the tests for Sodium (191).

Acidity or alkalinity—Dissolve 2.0 g 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. If no color appears, a pink color persists for 15 seconds is produced by not more than 0.2 mL of 0.10N sodium hydroxide. If the solution is colored pink by the addition of phenolphthalein TS, it is rendered colorless by not more than 0.50 mL of 0.1N sulfuric acid. Save the neutralized solution for the test for Fluosilicate.

Loss on drying (731)—Dry it at 150° for 4 hours: it loses not more than 1.0% of its weight.

Fluosilicate—After the solution from the test for Acidity or alkalinity has been neutralized, heat to boiling, and titrate while hot with 0.10N sodium hydroxide until a permanent pink color is obtained: not more than 1.5 mL of 0.10N sodium hydroxide is required.

Chloride—Dissolve 300 mg in 20 mL of water, and add 200 mg of boric acid, 1 mL of nitric acid, and 1 mL of 0.1 N silver nitrate: any turbidity produced is not greater than that of a blank to which has been added 1.0 mL of 0.0010 N hydrochloric acid (0.012%).

Heavy metals (231)—To 1 g, in a platinum dish or crucible, under a hood, add 1 mL of water and 3 mL of sulfuric acid, and heat at an a temperature as practicable until all of the sulfuric acid has been expelled. Dissolve the residue in 20 mL of water, neutralize the solution to phenolphthalein TS with ammonium hydroxide; add 1 mL of glacial acetic acid, dilute with water to 45 mL, filter, and use 30 mL of the filtrate for the test: the limit is 0.003%.

Organic volatile impurities, Method I (467): meets the requirements.

(Official until July 1, 2007)

Assay—[NOTE—Store all solutions, except the Buffer solution, in plastic containers.]

Buffer solution and Standard preparations—Prepare as directed in the Assay under Sodium Fluoride Oral Solution.
Sodium Fluoride Oral Solution

Sodium Fluoride Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of NaF.

Packaging and storage—Preserve in tight containers.

Labeling—Label the Tablets in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion. The Tablets that are to be chewed may be labeled as Sodium Fluoride Chewable Tablets.

USP Reference standards (11)—USP Sodium Fluoride RS.

Identification—
A: Disperse 20 finely powdered Tablets in 25 mL of water, shake, and filter: a portion of the filtrate responds to the tests for Sodium (191).

B: Evaporate a 10-mL portion of the filtrate obtained in Identification test A to dryness. To the residue add a mixture of 0.1 mL of freshly prepared sodium azide solution (1 in 1000) and 0.1 mL of a 1 in 1000 solution of zinc nitrate in 7N hydrochloric acid: a yellow color is produced.

Disintegration (701): 15 minutes.

Uniformity of dosage units (905): meet the requirements.

Assay—[NOTE—Store all solutions, except Buffer solution, in plastic containers.]

Buffer solution—Dissolve 57 g 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, dilute with water to 1000 mL, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Sodium Fluoride RS quantitatively in water to obtain a solution containing 420 µg per mL. Each mL of this solution (Standard preparation A) contains 190 µg of fluoride ion (10⁻³ M). Transfer 25.0 mL of Standard preparation A to a 250-mL volumetric flask, dilute with water to volume, and mix. This solution (Standard preparation B) contains 19 µg of fluoride ion per mL (10⁻⁴ M).

Transfer 25.0 mL of Standard preparation B to a 250-mL volumetric flask, dilute with water to volume, and mix. This solution (Standard preparation C) contains 1.9 µg of fluoride ion per mL (10⁻⁵ M).

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 10 mg of Fluoride, to a 500-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Pipet 20 mL of each Standard preparation and of the Assay preparation into separate plastic beakers each containing a plastic-coated stirring bar. Pipet 20 mL of Buffer solution into each beaker. Concomitantly measure the potentials (see pH (791)), in mV, of the solutions from the Standard preparations and of the solution from the Assay preparation, with a pH meter capable of a minimum reproducibility of ±0.2 mV and equipped with a fluoride-specific ion-indicating electrode and a calomel 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 to 2 minutes), 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 per mL, of the Standard preparations versus potential, in mV. From the measured potential of the Assay preparation and the standard response line, determine

then concentration, C, in µg per mL, of fluoride ion in the Assay preparation. Calculate the quantity, in mg, of fluoride ion in each mL of the Oral Solution taken by the formula:

\[
0.5(C/V)
\]

in which C is the determined concentration, in µg per mL, of fluoride ion in the Assay preparation, and V is the volume, in mL, of Oral Solution taken. Multiply the quantity of fluoride ion by 2.21 to obtain the quantity of NaF.

Sodium Fluoride Tablets

Sodium Fluoride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of NaF.

Packaging and storage—Preserve in tight containers.

Labeling—Label the Tablets in terms of the content of sodium fluoride (NaF) and in terms of the content of fluoride ion. The Tablets that are to be chewed may be labeled as Sodium Fluoride Chewable Tablets.

USP Reference standards (11)—USP Sodium Fluoride RS.

Identification—
A: Disperse 20 finely powdered Tablets in 25 mL of water, shake, and filter: a portion of the filtrate responds to the tests for Sodium (191).

B: Evaporate a 10-mL portion of the filtrate obtained in Identification test A to dryness. To the residue add a mixture of 0.1 mL of freshly prepared sodium azide solution (1 in 1000) and 0.1 mL of a 1 in 1000 solution of zinc nitrate in 7N hydrochloric acid: a yellow color is produced.

Disintegration (701): 15 minutes.

Uniformity of dosage units (905): meet the requirements.

Assay—[NOTE—Store all solutions, except Buffer solution, in plastic containers.]

Buffer solution and Standard preparations—Prepare as directed in the Assay under Sodium Fluoride Oral Solution. Assume preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of fluoride, to a plastic 500-mL conical flask containing 400 mL of water. Heat on a steam bath for 25 minutes with occasional shaking, cool to room temperature, and filter: a portion of the filtrate responds to the tests for Sodium (191).

Procedure—Proceed as directed for Procedure in the Assay under Sodium Fluoride Oral Solution. Calculate the quantity, in mg, of fluoride ion in the portion of Tablets taken by the formula:

\[
0.5C
\]

in which C is the determined concentration, in µg per mL, of fluoride ion in the Assay preparation. Multiply the quantity of fluoride ion by 2.21 to obtain the quantity of NaF.

Sodium Fluoride and Acidulated Phosphate Topical Solution

Sodium Fluoride and Acidulated Phosphate Topical Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fluoride ion.
Sodium Fluoride and Phosphoric Acid Solution

Sodium Fluoride and Phosphoric Acid Gel

Sodium Fluoride and Phosphoric Acid Gel contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fluoride ion, in an aqueous medium containing a suitable viscosity-inducing agent.

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.

Other requirements—It responds to the Identification tests under Sodium Fluoride and Phosphoric Acid Gel.

Assay—

Buffer solution and Standard preparations—Prepare as directed in the Assay under Sodium Fluoride Oral Solution.

Assay preparation—Transfer an accurately measured volume of the Standard preparation, equivalent to about 20 mg of fluoride ion, to a 1000-mL volumetric flask, add water to dissolve, dilute with water to volume, and mix.

Procedure—Proceed as directed for Procedure in the Assay under Sodium Fluoride Oral Solution. Calculate the quantity, in mg, of fluoride ion in each mL of the Topical Solution taken by the formula:

\[
\frac{C}{V}
\]

in which \( C \) is the determined concentration of fluoride ion, in \( \mu \)g per mL, in the Assay preparation, and \( V \) is the volume, in mL, of Topical Solution taken.

Sodium Fluoride and Phosphoric Acid Gel

Sodium Fluoride and Phosphoric Acid Gel contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fluoride ion, in an aqueous medium containing a suitable viscosity-inducing agent.

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.

Other requirements—It responds to the Identification tests under Sodium Fluoride and Phosphoric Acid Gel.

Assay—

Buffer solution and Standard preparations—Prepare as directed in the Assay under Sodium Fluoride Oral Solution.

Assay preparation—Transfer an accurately measured volume of the Standard preparation, equivalent to about 20 mg of fluoride ion, to a 1000-mL volumetric flask, add water to dissolve, dilute with water to volume, and mix.

Procedure—Proceed as directed for Procedure in the Assay under Sodium Fluoride Oral Solution. Calculate the quantity, in mg, of fluoride ion in each mL of the Topical Solution taken by the formula:

\[
\frac{C}{V}
\]

in which \( C \) is the determined concentration of fluoride ion, in \( \mu \)g per mL, in the Assay preparation, and \( V \) is the volume, in mL, of Topical Solution taken.

Sodium Fluoride and Phosphoric Acid Topical Solution

Sodium Fluoride and Phosphoric Acid Topical Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fluoride ion.

Packaging and storage—Preserve in tight, plastic containers.

Labeling—Label Topical 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 Fluoride RS.

Other requirements—It responds to the Identification tests under Sodium Fluoride and Phosphoric Acid Gel.

Assay—

Buffer solution and Standard preparations—Prepare as directed in the Assay under Sodium Fluoride Oral Solution.

Assay preparation—Transfer an accurately measured volume of the Standard preparation, equivalent to about 20 mg of fluoride ion, to a 1000-mL volumetric flask, add water to dissolve, dilute with water to volume, and mix.

Procedure—Proceed as directed for Procedure in the Assay under Sodium Fluoride Oral Solution. Calculate the quantity, in mg, of fluoride ion in each mL of the Topical Solution taken by the formula:

\[
\frac{C}{V}
\]

in which \( C \) is the determined concentration of fluoride ion, in \( \mu \)g per mL, in the Assay preparation, and \( V \) is the volume, in mL, of Topical Solution taken.

Sodium Gluconate

\[
\text{C}_6\text{H}_8\text{NaO}_7, \quad 218.14
\]

d-Gluconic acid, monosodium salt.

Monosodium D-gluconate \[527-07-1]\.

Sodium Gluconate contains not less than 98.0 percent and not more than 102.0 percent of \( \text{C}_6\text{H}_{11}\text{NaO}_7 \).