C_U = nominal concentration of sodium fluoride (NaF) in the *Sample solution* (µg/mL)
M_r = molecular weight of sodium fluoride, 41.99
A_r = atomic weight of fluoride, 19.00
Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS
- **pH ⟨791⟩:** 6.0–8.0. Place about 40 mL in a plastic beaker, and determine the pH using a suitable electrode system.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in tight, plastic containers.
- **Labeling:** Label the 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

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, plastic containers being used for Oral Solution having a pH below 7.5.

Labeling—Label 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 Fluoride RS

Identification—

A: Transfer 0.1 mL of Oral Solution to a small test tube, and add 0.1 mL of a freshly prepared mixture (1:1) of sodium alizarinsulfonate solution (1 in 1000) and zirconyl nitrate solution (1 in 1000) in 7 N hydrochloric acid: a yellow color is produced.

B: If necessary, reduce the volume of a portion of it by heating on a steam bath to a reduced volume containing about 10 mg of sodium per mL: the solution so obtained responds to the tests for *Sodium* ⟨191⟩.

Assay—[NOTE—Store all solutions, except *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, dilute with water to 1000 mL, and mix.

Standard preparations—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^{-2} 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^{-3} 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^{-4} 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 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 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 the 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 of fluoride, in µg per mL, 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

DEFINITION
Sodium Fluoride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of sodium fluoride (NaF).

IDENTIFICATION
- **A. Identification Tests—General,** *Sodium* ⟨191⟩
  Sample solution: Disperse 20 finely powdered Tablets in 25 mL of water, shake, and filter. Use the filtrate.
  Acceptance criteria: The filtrate meets the requirements.
- **B.**
  Sample solution: Evaporate a 10-mL portion of the filtrate obtained in *Identification* test *A* to dryness.
  Analysis: To the residue add a mixture of 0.1 mL of freshly prepared 1 mg/mL sodium alizarinsulfonate solution and 0.1 mL of 1 mg/mL zirconyl nitrate in 7 N hydrochloric acid.
  Acceptance criteria: A yellow color is produced.

ASSAY
- **Procedure**
  [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, equivalent to 190 µg/mL of fluoride ion (10^{-2} M)
  Standard solution B: 19 µg/mL of fluoride ion (10^{-3} M), from *Standard solution A*
  Standard solution C: 1.9 µg/mL of fluoride ion (10^{-4} M), from *Standard solution B*
  Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder equivalent to 10 mg of fluoride to a plastic 500-mL conical flask containing 400 mL of water. Heat on a steam bath for 25 min with occasional shaking, and cool to room temperature. Transfer to a 500-mL volumetric flask, and dilute with water to volume.