V_{S} = volume of *Titrant* consumed by the *Sample* (mL) = volume of *Titrant* consumed by the *Blank* (mL) = actual normality of the *Titrant* (mEq/mL) V_R Ň = equivalency factor, 144.1 mg/mEq W = weight of the *Sample* (mg) **Acceptance criteria:** 99.0%–100.5% on the anhydrous basis

IMPURITIES

HEAVY METALS (231)

Test preparation: 4.0 g in 40 mL of water

Analysis: To the *Test preparation* add dropwise with vigorous stirring 10 mL of 3 N hydrochloric acid, and filter. Use 25 mL of the filtrate.

Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS

• WATER DETERMINATION, Method I (921): NMT 1.5%

ALKALINITY

Sample solution: 2 g in 20 mL of hot water Analysis: To the Sample solution add 2 drops of phenolphthalein TS.

Acceptance criteria: The pink color produced, if any, is discharged by the addition of 0.20 mL of 0.10 N sulfuric

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in well-closed containers.

• USP REFERENCE STANDARDS $\langle 11 \rangle$ USP Sodium Benzoate RS

Sodium Bicarbonate—see Sodium Bicarbonate General Monographs

Sodium Borate

381.37 $Na_2B_4O_7 \cdot 10H_2O$

201.22 Na₂B₄O₇

Borax [1303-96-4]. Anhydrous [1330-43-4].

DEFINITION

Sodium Borate contains an amount of Na₂B₄O₇ equivalent to NLT 99.0% and NMT 105.0% of Na₂B₄O₇ · 10H₂O.

IDENTIFICATION

• A. IDENTIFICATION TESTS—GENERAL, Sodium (191) Sample solution: 1 in 20

Acceptance criteria: Meets the requirements B. Identification Tests—General, Borate (191)

Sample solution: 1 in 20

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Sample: 3 g of Sodium Borate

Titrimetric system (See *Titrimetry* (541).) **Mode**: Direct titration

Titrant: 0.5 N hydrochloric acid VS

Blank: 50 mL of water

Endpoint detection: Visual **Analysis:** Dissolve the *Sample* in 50 mL of water, add methyl red TS, and titrate with 0.5 N hydrochloric acid VS. [NOTE-Heating on a steam bath may be required initially to effect solution.]

Calculate the percentage of sodium borate (Na₂B₄O₇ · 10H₂O) in the Sample taken:

Result =
$$[(V - B) \times N \times F] \times 100/W$$

= volume of *Titrant* consumed by the *Sample* (mL) R = volume of *Titrant* consumed by the *Blank* (mL)

Ν = actual normality of the Titrant (mEq/mL)

= equivalency factor, 190.7 mg/mEq W

= weight of the Sample (mg) Acceptance criteria: 99.0%–105.0%

IMPURITIES

• HEAVY METALS (231)

Test preparation: Dissolve 1 g in 16 mL of water and 6 mL of 1 N hydrochloric acid. Dilute with water to 25 mL. Acceptance criteria: NMT 20 ppm

CARBONATE AND BICARBONATE

Sample solution: To 5 mL of a solution (1 in 20), contained in a test tube, add 1 mL of 3 N hydrochloric acid. Acceptance criteria: No effervescence is observed.

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in tight containers.

Sodium Caprylate



C₈H₁₅NaO₂ 166.20

[1984-06-1]. Sodium octanoate

» Sodium Caprylate contains not less than 99.0 percent and not more than 101.0 percent of $C_8H_{15}NaO_2$, calculated on the anhydrous basis.

USP Reference standards (11)—

USP Caprylic Acid RS

Appearance of solution—Dissolve 2.5 g of Sodium Caprylate in 25.0 mL of freshly boiled and cooled water: the resulting solution is clear and colorless, and if not, not more intensely colored than a reference solution prepared as follows:

Reference stock solution-Pipet 30.0 mL of ferric chloride CS, 30.0 mL of cobaltous chloride CS, and 24.0 mL of cupric sulfate CS into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume, and mix.

Reference solution—Pipet 1.0 mL of the Reference stock solution into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume, and mix.

A: The retention time of the major peak in the chromatogram of Test solution 1 corresponds to that in the chromatogram of the Reference solution, as obtained in the test for Chromatographic purity.

B: Proceed as directed below.

Methoxyphenylacetic reagent—Dissolve 2.7 g of methoxyphenylacetic acid in 6 mL of 10% tetramethylammonium hydroxide solution in methanol, and add 20 mL of alcohol. Store in a polyethylene container.

Procedure—Dissolve about 20 mg of Sodium Caprylate in 0.5 mL of water, add 1.5 mL of Methoxyphenylacetic reagent, and cool in ice water for 30 minutes. A voluminous, white, crystal-line precipitate is formed. Place in water at 20°, and stir for 5 minutes. The precipitate does not disappear. Add 1 mL of ammonia TS. The precipitate dissolves completely. Add 1 mL of ammonium carbonate solution (16 in 100): no precipitate is formed.

pH (791): between 8.0 and 10.5, in a solution obtained in the test for Appearance of solution.