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Sodium Hypochlorite Compounded Topical Solution

DEFINITION
Sodium Hypochlorite Compounded Topical Solution contains NLT 0.20 g and NMT 0.32 g of sodium hypochlorite (NaClO) in 1000 mL of Topical Solution.
Prepare Sodium Hypochlorite Compounded Topical Solution as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

| | |
|---|---------|
| Sodium Hypochlorite Solution | 5.0 mL |
| Monobasic Sodium Phosphate, monohydrate | 1.02 g |
| Dibasic Sodium Phosphate, anhydrous | 17.61 g |
| Purified Water, a sufficient quantity to make | 1000 mL |

Dissolve the *Dibasic Sodium Phosphate, anhydrous* and the *Monobasic Sodium Phosphate, monohydrate* in about 500 mL of *Purified Water*. Add the *Sodium Hypochlorite Solution* and sufficient *Purified Water* to bring the preparation to final volume, and mix.
[NOTE—The source of the *Sodium Hypochlorite Solution* may be commercial unscented laundry bleach, nominally 5.25% (w/v) provided that the commercial laundry bleach was acquired recently.]

ASSAY
• **PROCEDURE**
Sample: 50.0 mL
Titrimetric system
Mode: Direct titration
Titrant: 0.1 N sodium thiosulfate VS
Endpoint detection: Visual
Analysis: To the *Sample* in a glass-stoppered flask add 0.5 g of potassium iodide and 10 mL of 6 N acetic acid. Titrate the liberated iodine with *Titrant*, adding 2 mL of starch TS as the endpoint is approached. Perform a blank determination and make any necessary correction. Each mL of *Titrant* is equivalent to 3.722 mg of sodium hypochlorite (NaClO).
Acceptance criteria: 0.20–0.32 g in 1000 mL

SPECIFIC TESTS
• **pH (791):** 7.8–8.2

ADDITIONAL REQUIREMENTS
• **PACKAGING AND STORAGE:** Package in tight, light-resistant, 1-L plastic containers, and store at controlled room temperature.
• **BEYOND-USE DATE:** NMT 7 days after the date on which it was compounded when stored at controlled room temperature
• **LABELING:** Label it to indicate that its strength is 0.025%, and to state the *Beyond-Use Date*. [NOTE—For external use only; it may be applied to wounds and burns.]

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|--------------------------|
| SODIUM HYPOCHLORITE COMPOUNDED TOPICAL SOLUTION | Brian Serumaga Science Program Manager | CMP2020 Compounding 2020 |

| Topic/Question | Contact | Expert Committee |
|----------------------------|---|--------------------------|
| REFERENCE STANDARD SUPPORT | RS Technical Services RSTECH@usp.org | CMP2020 Compounding 2020 |

Chromatographic Database Information: [Chromatographic Database](#)

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