



SUGGESTED FORMULA

Tetracaine Hydrochloride 2% Oral-Topical Solution, Preserved

Version number: 1.0 Volume: 100 mL

Tetracaine HCl, USP (TE128) 2 gm
Chlorobutanol, Anhydrous, NF (CH123) 0.4 gm
Purified Water, USP (W1014) Q.S. 100 mL

*If using orally, this formulations has a slightly bitter taste. A cherry or other sweetened flavor may improve palatability.

SUGGESTED COMPOUNDING PROCEDURES

- 1. Calculate the required quantity of each ingredient for the total amount to be prepared.
- 2. Accurately weigh and/or measure each ingredient.
- 3. In calibrated beaker add approximately 50% of final volume of Purified Water.
- 4. Dissolve Tetracaine Hydrochloride and Chlorobutanol in step 3.
- 5. Bring to volume with Purified water and mix until homogenous.
- 6. Package and label.
- 7. Suggested Quality Assessments follow pharmacy SOPs:
 - a. Clarity
 - b. Color
 - c. Homogenous

Store in air tight amber plastic containers.

Store at room temperature.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date should be assigned using the current USP <795> Guidelines

Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (hoods) when weighing and mixing.

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