

## SUGGESTED PROCEDURE

|                 |                           |               |                    |
|-----------------|---------------------------|---------------|--------------------|
| Item            | Tetracaine 4.0% Lollipops | Formula Date  | 12 Nov 2024        |
| API(s)          | Tetracaine Hydrochloride  | Procedure No. | P2709              |
| Base            | Krystal SF™               | Revision      | R4                 |
| Volume/Quantity | 10 Lollipops              | Compound Type | Anhydrous Lollipop |

| Rx   | Weight (g)   | Percent     | Comment  |
|--|--------------|-------------|--|
| Tetracaine HCl, USP                                      | 3.05g        | 4.0%        | Melting point roughly 148°C  |
| Krystal SF™  | 72.85g       | 95.5%       | qs Approx density in finished candy state: 1.36-1.40 g/cm <sup>3</sup> |
| SpecializedRx WS<br>Natural Liquid Flavor<br>Concentrate | 0.4ml        | 0.5%        | To taste   |
|  |              |             |  |
| <b>Total</b>   | <b>76.3g</b> | <b>100%</b> |  |

Average Krystal SF™ calibration placebo weight using SmartPops™ Lollipop molds is 7.63g per mold cavity.

To account for processing error considerations during preparation, it is suggested to measure an additional **10%** of the required quantities of ingredients.

### Suggested Method of Preparation

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient. Account for batch size and density conversions, if required.
3. Melt the Krystal SF™ base at 145-150°C (hard crack stage). Do not overheat.
4. Remove from heat and allow to cool to 140 °C.
5. Slowly add Tetracaine HCl powder to the base, making sure to prevent clumping and ensuring addition is wetted before adding additional powder while maintaining a good working temperature. Mix thoroughly.
6. Krystal SF™ is workable down to roughly 115°C before it will start to harden.
7. Pour the mixture in the molds or fill individual cavities with a large capacity glass pipette, quickly filling each cavity.
8. Set times will vary. Allow to cool at room temperature. Rapid cooling can lead to cracking and surface deformation. Generally hard to the touch in 20-30 minutes and hard set in less than two hours.
9. Apply CR cap and label.
10. Suggested Quality assessments
  - a. Appearance and feel
  - b. Quantity
  - c. Label: auxiliary labels, storage, BUD, compounded medication, for external use only

**Packaging:** Tight, light-resistant container, SmartPops™

**Estimated Beyond Use Date:** 180 days per USP 795\*

**Labeling:** Keep out of reach of children. Use only as directed. Protect from moisture and light.

**Stability:** Anhydrous formulation.

**Note:** Potency Range Recommendation: ≥90% and ≤110% of the theoretically calculated active(s).

\*Beyond-Use Date should be based on the current USP General Chapter <795>. Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounding and contamination of the preparation by the compounding. 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.

**WARNING!** Precautions should be taken when handling APIs as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.

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