SpecializedRx
3787 95th Ave NE, Ste 100
Circle Pines, MN. 55014 USA
888.512.1209
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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/cm³
SpecializedRx WS Natural Liquid Flavor Concentrate	0.4ml	0.5%	To taste
Total	76.3g	100%	

Average Krystal SF™ calibration placebo weight using SmartPopps™ 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, SmartPopps™
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 compounder and contamination of the preparation by the compounder. 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.

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