SpecializedRx
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SUGGESTED PROCEDURE

Item	Calcipotriol 0.005% Fluorouracil 5% Anhydrous Topical Preparation	Formula Date	01 Jul 2022
API(s)	Calcipotriol / 5-Fluorouracil	Procedure No.	P2572
Base	Angelsil™ Anhydrous	Revision	R1
Volume/Quantity	30g	Compound Type	Anhydrous Topical

Rx	Weight (g)	Percent	Comment
Calcipotriol, USP	0.0015	0.005%	
5-Fluorouracil, USP	1.5	5.000%	
Angelsil™ Anhydrous	27.4985	91.662%	qs
Propylene Glycol	1.0	3.333%	
Total	30.00	100.000%	

To account for processing error considerations during preparation, it is suggested to measure an additional **12 to 15%** 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. Take into account batch size and density conversions, if required.
3. Powder/liquid preparation: Triturate the Calcipotriol and 5-Flurooouacil to form a fine, homogeneous powder.
4. Levigate the fine, homogeneous powder with Propylene Glycol to form a homogeneous paste dispersion.
5. Incrementally add the homogeneous paste dispersion to the Angelsil™ Anhydrous Base. Continuously mix, using high-shear mixing to form a homogeneous gel-like dispersion. Suggest using an UnoDose® mixing/dispensing container for preparation compounding and dispensing.
6. If the final preparation is gritty, pass it through an ointment mill until it becomes smooth and uniform.
7. Transfer the final preparation into an appropriate dispensing container.
8. 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, syringe, UnoDose container.
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.

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.