

SUGGESTED PROCEDURE

Item	Cysteamine Hydrochloride 5%	Formula Date	30 OCT 2025
API(s)	Cysteamine HCl, USP	Procedure No.	P2744
Base	PentraCream™	Revision	R01
Volume/Quantity	30 g	Compound Type	Anhydrous Cream

Rx	Weight (g)	Percent	Comment
Cysteamine HCl, USP	1.5 g	5%	
Ascorbic Acid, USP	0.9 g	3%	
Ethoxy Diglycol, NF	0.9 g	3%	
PentraCream™	26.7 g	89%	qs
Total	30 g	100%	

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. Consider batch size and density conversions if required.
3. Triturate active ingredients to a fine powder.
4. Geometrically incorporate the actives into the PentraCream™ and mix well to form a homogeneous cream-like dispersion.
5. Alternately mix using an ungator or planetary mixer.
6. Final product should be a uniform, smooth cream.
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

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).

Note: All products, except for API(s) are sourced from SpecializedRx only. Any deviation from ingredients used will invalidate the formula.

***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.

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