

SUGGESTED PROCEDURE

Item	Estradiol 10%	Formula Date	12 Dec 2023
API(s)	Estradiol, USP	Procedure No.	P2631
Base	VersaCream™ PRO	Revision	R1
Volume/Quantity	100g	Compound Type	Hydrous Topical

Rx	Weight (g)	Percent	Comment
Estradiol, USP	10g	10%	
Ethoxy Diglycol, NF	5ml	5%	
VersaCream™ PRO	85g	85%	qs
Total	100g	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. Levigate the Estradiol powder with Ethoxy Diglycol to form a homogeneous paste dispersion.
4. Geometrically incorporate the VersaCream™ PRO and mix well using high-shear to form a homogeneous cream-like dispersion.
5. Final product should be uniform and smooth with a slight sheen.
6. Transfer the final preparation into an appropriate dispensing container.
7. 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: 35 days per USP 795*

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

Stability: Hydrous 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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