



Suggested Formula	Betamethasone Valerate 0.12%, Tranilast 1% Topical Gel (Suspension, 100 g)	FIN	F 006 353
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**Note:** Betamethasone Valerate 0.12% is equivalent to Betamethasone 0.1%.

### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Betamethasone Valerate (Micronized), USP	0.120	g				
Tranilast	1.000	g				
Propylene Glycol, USP	5.0	mL				
Medisca CopaSil™	93.69	g				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light sensitive** (protect from light whenever possible):

*Tranilast, Propylene Glycol*

**Hygroscopic** (protect from moisture whenever possible):

*Propylene Glycol*

#### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

#### Processing Error /

#### Testing Considerations:

To account for processing error during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

#### Special Instruction:

Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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**SUGGESTED PREPARATION (for 100 g)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Betamethasone Valerate (Micronized), USP	0.120	g			
Tranilast §	1.000	g			
Propylene Glycol, USP §	5.0	mL			
Medisca CopaSil™	93.69	g			

§ Weigh / measure just prior to use.

\* Takes into account increased batch size conversions and density conversions, if required.

**Preparatory Instruction**

1.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. By geometrical addition, combine and triturate the following ingredients together to form a fine homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Betamethasone Valerate (Micronized)</li> <li>-Tranilast</li> </ul> <p>B. Levigate the fine, homogeneous powder blend (Step 1A) with the Propylene Glycol.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
2.	<p><b><u>Powder-liquid to medium integration:</u></b></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the CopaSil™.</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p> <p>B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.</p>
3.	<p><b><u>Product transfer:</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>



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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date		Packaging Requirements	
	6 months, as per USP*.		- Tightly closed, light-resistant container. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6
	2	May produce psychological and/or physical dependence.	7
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8
	4	Keep in a dry place.	9
	5	Keep out of reach of children.	10
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.		
Patient Instructions	Contact your pharmacist in the event of adverse reactions. <b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.		

\* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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## REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 265.
2.	Betamethasone Valerate. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1519.
3.	Tranilast. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1149.
4.	Betamethasone (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #1182.
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6.	Betamethasone . In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 64.
7.	Betamethasone Valerate (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 2422.
8.	USP <795>. <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2013: 559.

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