



Suggested Formula	Chlorhexidine Gluconate 0.5%, Miconazole 2% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 824v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Chlorhexidine Gluconate Solution (20%), USP	2.50	mL				
Miconazole, USP	2.000	g				
Ethoxy Diglycol	2.0	mL				
Medisca U-Mild™ Shampoo Base	70.0	mL				
Purified Water, USP	q.s. to 100.0	mL	⊕			

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light sensitive (protect from light whenever possible): *Chlorhexidine Gluconate Solution, Miconazole*

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations 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 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Chlorhexidine Gluconate Solution (20%), USP §	2.50	mL			
Miconazole, USP §	2.000	g			
Ethoxy Diglycol §	2.0	mL			
Medisca U-Mild™ Shampoo Base	70.0	mL			
Purified Water, USP	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1. Powder-liquid preparation:

- A. Triturate the Miconazole to form a fine, homogeneous powder.
- B. Levigate the fine, homogeneous powder (Step 1A) with the Ethoxy Diglycol.

End result: Homogeneous paste-like dispersion.

2. Powder-liquid to medium integration:

- A. In the given order, sequentially add the following ingredients to the U-Mild™ Shampoo Base:
 - Chlorhexidine Gluconate Solution (20%)
 - Homogeneous paste-like dispersion (Step 1B)

Specifications: Continuously mix until homogenous.

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.



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3.	<p><u>Filling to volume:</u></p> <p>A. Add Purified Water to the mixture (Step 2A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
4.	<p><u>Product transfer:</u></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process in order to maintain homogeneity.</p>

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	30 days, as per USP.		Packaging Requirements	- Tightly closed, light-resistant topical dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.
	2	For veterinary use only.	7	Gently mix until homogenous before use.
	3	Keep out of reach of children.	8	Protect from light.
	4	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	For external use only.
	5	Keep at room temperature (20°C – 23°C).		
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. IMPORTANT: The quantity of API administered is directly dependent on the quantity of product applied.			



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REFERENCES

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