



Suggested Formula	Methimazole 5 mg/0.1 mL Transdermal PLO Gel (Emulsion, 6.5 mL)	FIN	F 006 918
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Methimazole, USP	0.325	g				
Medisca PLO Gel Mediflo™ (Pre-Mixed)	0.5	mL				
Medisca PLO Gel Mediflo™ (Pre-Mixed)	q.s. to 6.5	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible):

Methimazole

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 **25 to 30%** 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 6.5 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : _____	Processing Error	Qty. to measure
Methimazole, USP §	0.325	g			
Medisca PLO Gel Mediflo™ (Pre-Mixed)	0.5	mL			
Medisca PLO Gel Mediflo™ (Pre-Mixed)	q.s. to 6.5	mL			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Methimazole to form a fine, homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 1A) with the PLO Gel Mediflo™ (Pre-Mixed) (0.5 mL <i>plus</i> processing error adjustments).</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p>
2.	<p><u>Filling to volume:</u></p> <p>A. Add additional PLO Gel Mediflo™ (Pre-Mixed) to the homogeneous gel-like dispersion (Step 1A) to fill to the required batch size (6.5 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p>
3.	<p><u>Product transfer:</u></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	
	30 days, as per USP.		MD™ Pen (6.5 mL, 0.10 mL Metered Dose)
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 For veterinary use only.
	2	Keep out of reach of children.	7 For external use only.
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	8 May impair mental and/or physical ability.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9 Keep at room temperature (20°C – 23°C).
	5	Protect from light.	
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

1.	Gels. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 285.
2.	Tapazole. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2015</i> : 2896.
3.	Thiamazole. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2176.
4.	Methimazole (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #6043.
5.	Methimazole. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 316.
6.	Methimazole (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 4792.
7.	Methimazole. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 453.
8.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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