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Suggested Formula	Diltiazem Hydrochloride 2%, Lidocaine Hydrochloride 5% Mucoadhesive Rectal Gel (Suspension, 50 g)	FIN	F 008 265v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Diltiazem Hydrochloride, USP	1.000	g				
Lidocaine Hydrochloride, USP	TBD					
Glycerin, USP	3.0	mL				
Medisca NovaFilm™ Gel Base	20.0	mL				
Medisca VersaPro™ Gel Base	TBD					





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**SPECIAL PREPARATORY CONSIDERATIONS**

Ingredient-Specific Information

**Light Sensitive** (protect from light whenever possible): *Diltiazem Hydrochloride, NovaFilm™ Gel Base*

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

**Narrow Therapeutic Index** *Lidocaine Hydrochloride*

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 **10 to 12%** of the required quantities of ingredients.

Special Instruction: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: <https://www.usp.org/usp-800-context-for-implementation-fs.pdf>.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFI) and Compliance Policy Guides (CPGs).

**Lidocaine Hydrochloride has a Narrow Therapeutic Index.**

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 50 g)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Diltiazem Hydrochloride, USP §	1.000	g			
Lidocaine Hydrochloride, USP	TBD				
Glycerin, USP §	3.0	mL			
Medisca NovaFilm™ Gel Base §	20.0	mL			
Medisca VersaPro™ Gel Base	TBD				

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

§ Weigh / measure just prior to use.

Preparatory Instruction

**1. Ingredient quantification:**

A. Determine the potency of Lidocaine Hydrochloride based on the certificate of analysis:

MINUS	100%
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Lidocaine Hydrochloride, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
<b>i. Potency of Lidocaine Hydrochloride, in decimal</b>	_____



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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Lidocaine Hydrochloride required to make a Lidocaine Hydrochloride 5% Mucoadhesive Gel, batch size (50 g):

Quantity of Lidocaine Hydrochloride required for 50 g	2.500 g
DIVIDED BY	
Potency of Lidocaine Hydrochloride, in decimal (Step 1Ai)	_____
EQUALS	
<b>i. Quantity of Lidocaine Hydrochloride needed for 50 g</b>	_____ g
MULTIPLIED BY	
Processing error adjustments (10 to 12%)	1.10 to 1.12
EQUALS	
<b>ii. Quantity of Lidocaine Hydrochloride needed <i>plus</i> processing error adjustments</b>	_____ g



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3. **Ingredient quantification:**

A. Determine the actual quantity of VersaPro™ Gel Base to weigh for the required batch size (50 g):

Total Weight of the batch	50.00 g
MINUS	
Total amount of other ingredients except Lidocaine Hydrochloride	25.69 g
MINUS	
The weight of Lidocaine Hydrochloride (Step 2Ai)	_____ g
EQUALS	
<b>i. Quantity of VersaPro™ Gel Base needed for 50 g</b>	_____ g
MULTIPLIED BY	
Processing error adjustments (10 to 12%)	1.10 to 1.12
EQUALS	
<b>ii. Weight of VersaPro™ Gel Base required <i>plus</i> processing error adjustments</b>	_____ g

4. **Powder-liquid preparation:**

A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

- Diltiazem Hydrochloride
- Lidocaine Hydrochloride (amount determined in Step 2Ai)

B. Levigate the fine homogeneous powder blend (Step 4A) with the Glycerin.

End result: Homogeneous paste-like dispersion.



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5.	<p><b><u>Powder-liquid to Base integration:</u></b></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 4B) to the VersaPro™ Gel Base (amount determined in Step 3Aii).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p>
6.	<p><b><u>NovaFilm™ Gel Base addition:</u></b></p> <p>A. Incrementally add the NovaFilm™ Gel Base to the homogeneous gel-like dispersion (Step 5A).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p>
7.	<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	30 days, as per USP 795.	Packaging Requirements	- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Protect from light.
	2	Keep out of reach of children.	7	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	For mucosa use only (rectal).	8	Cap tightly after use.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9	Keep in a dry place.
	5	Keep at controlled room temperature (20°C – 25°C).	10	May impair mental and or physical ability. Use care when operating a car or machinery.
Pharmacist Instructions	<p>Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.</p> <p><b>IMPORTANT:</b> - Small batch is prepared due to inherent potential of systemic toxicity.</p> <ul style="list-style-type: none"> <li>- Limits as to the total amount of product used should be established by a physician.</li> <li>- You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas.</li> <li>- Continued application of this product might produce systemic side effects. Advise patient accordingly.</li> </ul> <p><b>IMPORTANT: DRUG-DRUG INTERACTION EXISTS BETWEEN DILTIAZEM HYDROCHLORIDE AND LIDOCAINE HYDROCHLORIDE. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.</b></p>			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p><b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.</p>			



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## REFERENCES

1.	Gels. In: Allen, LV, Jr. <i>The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition</i> . American Pharmacists Association; 2016: 339.
2.	Diltiazem Hydrochloride. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1265
3.	Lidocaine Hydrochloride. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1862.
4.	Diltiazem (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #3224.
5.	Lidocaine (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #5535.
6.	Diltiazem Hydrochloride. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 168.
7.	Lidocaine Hydrochloride. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 288.
8.	Diltiazem Hydrochloride (Monograph). <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 1370.
9.	Lidocaine Hydrochloride (Monograph). <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2569.
10.	USP <795>. <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6951.

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