MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
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technicalservices@medisca.net

Suggested Formula	Lidocaine Hydrochloride 5% Mucoadhesive Oral Gel (Suspension, 100 g)	FIN	F 008 448

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lidocaine Hydrochloride, USP	TBD					
Mineral Oil (Light), NF	5.0	mL				
Medisca NovaFilm™ Gel Base	30.0	mL				
Medisca NovaFilm™ Gel Base	TBD					

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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 **5 to 9%** 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 (GFIs) 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 100 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Lidocaine Hydrochloride, USP	TBD				
Mineral Oil (Light), NF §	5.0	mL			
Medisca NovaFilm™ Gel Base §	30.0	mL			
Medisca NovaFilm™ 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:

	100%
MINUS	
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	
i. Potency of Lidocaine Hydrochloride, in decimal	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Lidocaine Hydrochloride required to make a Lidocaine Hydrochloride 5% Mucoadhesive Oral Gel, batch size (100 g):

Quantity of Lidocaine Hydrochloride required for 100 g	5.000 g
DIVIDED BY	
Potency of Lidocaine Hydrochloride, in decimal (Step 1Ai)	_____
EQUALS	
i. Quantity of Lidocaine Hydrochloride needed for 100 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Lidocaine Hydrochloride needed *plus* processing error adjustments	_____ **g**

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3. **Ingredient quantification:**

A. Determine the additional quantity of NovaFilm™ Gel Base to weigh for the required batch size (100 g):

Total Weight of the batch	100.00 g
MINUS	
Total amount of other ingredients except Lidocaine HCl	35.595 g
MINUS	
The weight of Lidocaine Hydrochloride (Step 2Ai)	_____ g
EQUALS	
i. Quantity of NovaFilm™ Gel Base needed for 100 g	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Weight of NovaFilm™ Gel Base required *plus* processing error adjustments	_____ g

4. **Powder-liquid preparation:**

A. Triturate the Lidocaine Hydrochloride (amount determined in Step 2Aii) to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 4A) with the Mineral Oil (Light).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous paste-like dispersion.

5. **Powder-liquid to Base integration:**

A. Incrementally add the NovaFilm™ Gel Base (30.0 mL *plus* processing error adjustments) to the homogeneous paste-like dispersion (Step 4B).

Specifications: Continuously mix until homogeneous.

End result: Homogeneous liquid-like dispersion.

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6.	**Filling to Batch Size:** A. Add additional NovaFilm™ Gel Base (amount determined in Step 3Aii) to the homogeneous liquid-like dispersion (Step 5A) to fill to the required batch size (100.00 g *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion.
7.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP	Packaging Requirements		Tightly closed, light-resistant ointment tube/jar with oral applicator.
Auxiliary Labels9	1	Use as directed. Do not exceed prescribed dose.	6		May impair mental and/or physical ability. Use care when operating a car or machinery.
	2	Keep out of reach of children.	7		Cap tightly after use.
	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		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep at controlled room temperature (20°C – 25°C).	9		For oral (local) use only. Do not swallow.
	5	Protect from light.	10		Keep in a dry place.
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT:** - Small batch is prepared due to inherent potential of systemic toxicity. - Limits as to the total amount of product used should be established by a physician. - You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas. - Continued application of this product might produce systemic side effects. Advise patient accordingly.			
Patient Instructions		Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** - Do not cover the site of application. - The quantity of active ingredient administered is directly dependent on the quantity of product applied.			

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REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 317.
2.	Lidocaine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1862.
3.	Lidocaine Hydrochoride (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #1862.
4.	Lidocaine Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 288.
5.	Lidocaine Hydrochloride (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2569.
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