



Suggested Formula	Lidocaine 10%, Prilocaine 10%, Tetracaine 4% Dental Paste (Emulsion, 30 g)	FIN	F 006 065v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lidocaine, USP	3.000	g				
Prilocaine, USP	3.000	g				
Tetracaine, USP	1.200	g				
Stevia Powder	0.10	g				
Butylated Hydroxytoluene (BHT), NF	0.03	g				
Bubble Gum Flavor	0.3	mL				
Medisca OleaBase™ Plasticized	22.37	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Narrow Therapeutic Index

Lidocaine

Eutectic Mixture when combined:

Lidocaine, Prilocaine, Tetracaine

Light sensitive (protect from light whenever possible):

Tetracaine, Butylated Hydroxytoluene

Hygroscopic (protect from moisture whenever possible):

Stevia Powder

Moisture sensitive (protect from humidity whenever possible):

Butylated Hydroxytoluene

Heat Sensitive (protect from heat whenever possible):

Butylated Hydroxytoluene

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 **12 to 15%** 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.

Lidocaine 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 30 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : _____	Processing Error	Qty. to measure
Lidocaine, USP	3.000	g			
Prilocaine, USP	3.000	g			
Tetracaine, USP §	1.200	g			
Stevia Powder §	0.10	g			
Butylated Hydroxytoluene (BHT), NF §	0.03	g			
Bubble Gum Flavor	0.3	mL			
Medisca OleaBase™ Plasticized	22.37	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1. **Preparatory step:**

A. Prepare a hot water bath.

Specifications: Temperature: 40 to 45°C.



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2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and triturate the following ingredients together:</p> <ul style="list-style-type: none">-Lidocaine-Prilocaine-Tetracaine <p><u>Specifications:</u> Continuously mix. Heat to 40~45°C in the water bath to dissolve if necessary.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>B. In the given order, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 2A):</p> <ul style="list-style-type: none">-Stevia Powder-Butylated Hydroxytoluene (BHT)-Bubble Gum Flavor <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><u>Medium Integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 2B) to the OleaBase™ Plasticized.</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p> <p><u>Note:</u> If the paste is gritty, pass through an ointment mill until a smooth, homogeneous paste is obtained.</p>
4.	<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.		Tightly closed, light-resistant unit dose syringe.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep at room temperature (20°C – 23°C).
	2	Keep out of reach of children.	7	For external use only.
	3	Discard the syringe after use.	8	Keep in a dry place.
	4	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	10	Protect from light.
Pharmacist Instructions	<p>Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.</p> <p>IMPORTANT: - Small batch is prepared due to inherent potential of systemic toxicity.</p> <ul style="list-style-type: none"> - 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. <p>IMPORTANT: DRUG-DRUG INTERACTIONS EXISTS BETWEEN LIDOCAINE AND PRILOCAINE. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.</p>			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p>IMPORTANT: - The quantity of active ingredient administered is directly dependent on the quantity of product applied.</p> <ul style="list-style-type: none"> - Do not cover the site of application. 			



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REFERENCES

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7.	Tetracaine (Monograph). In: O'Neil MJ. <i>The Merck Index 14th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #9188.
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