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Suggested Formula	Lidocaine 4% Oral Adhesive Powder (Powder Blend, 10 g)	FIN	F 007 423
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lidocaine, USP	0.400	g				
Stevia Powder	0.10	g				
Polyox™ WSR-301 Topical Adhesive Powder*	9.50	g				

*Formula # F 007 422 available on request.





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): *Stevia Powder, Polyox™ WSR-301 Topical Adhesive Powder*

Narrow Therapeutic Index *Lidocaine*

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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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 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 10 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Lidocaine, USP	0.400	g			
Stevia Powder §	0.10	g			
Polyox™ WSR-301 Topical Adhesive Powder §	9.50	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1. Powder preparation: A. Pass the Polyox™ WSR-301 Topical Adhesive Powder through a 40 or 50-mesh sieve and weigh the required quantity. B. Combine and mix (DO NOT TRITURATE), using a manual tumbler mixer, the following ingredients together to form a homogeneous powder blend: -Lidocaine -Stevia Powder - Polyox™ WSR-301 Topical Adhesive Powder (Step 1A) <u>Note:</u> Do not use excessive force, as Polyox™ WSR-301 Topical Adhesive Powder should not be triturated.
2. Product transfer: Transfer the final product into the specified dispensing container (see “Packaging requirements”).



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	Tightly closed, suitable powder package.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	May impair mental and/or physical ability. Use care when operating a car or machinery.	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Keep at room temperature (20°C – 23°C).	8	For local (oral) use only.
	4	Cap tightly after use.	9	Keep in a dry place.
	5	Keep out of reach of children.		
Pharmacist Instructions	<p>Note: This non-sterile formulation, as per USP <3>, should not be applied to an open wound or burned area. If this formulation will be applied to an open wound or burned area, it must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP <797>. Also, in consideration of the overall formulation make-up and following the manufacturer’s specifications, the suggested method of end-stage sterilization is gamma irradiation. The resulting BUD will be 30 days, as per USP <797>, based on a successful sterility test result.</p> <p>Add any auxiliary labels specific to the API 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. 			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p>IMPORTANT: - Do not cover the site of application.</p> <ul style="list-style-type: none"> - The quantity of API administered is directly dependent on the quantity of product applied. 			

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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REFERENCES

1.	Powders and Granules. In: Allen, LV, Jr. <i>The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition</i> . American Pharmacists Association; 2016: 173.
2.	Xylocaine Ointment 5%. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2017</i> : 3949.
3.	Lidocaine. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1862.
4.	Lidocaine (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #5535.
5.	Lidocaine (Monograph). <i>United States Pharmacopeia XL / National Formulary 35</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2017: 4845.
6.	Lidocaine. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 196.
7.	USP <795>. <i>United States Pharmacopeia XL / National Formulary 35</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2017: 675.

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