



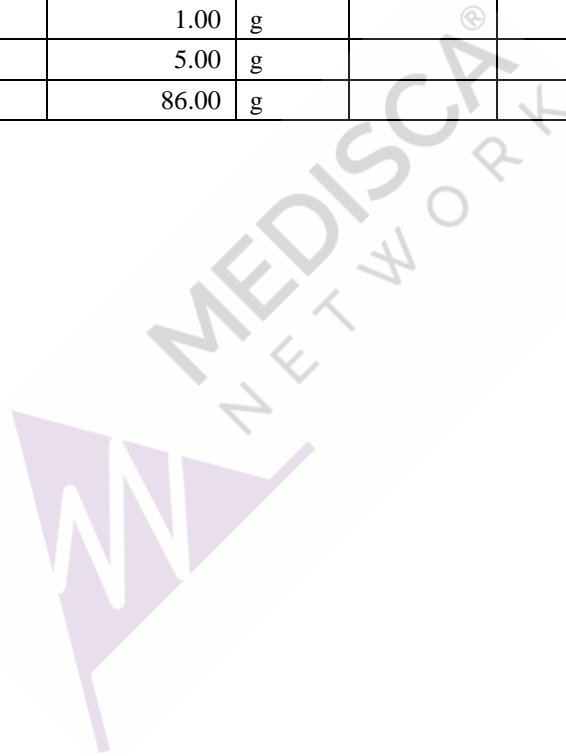
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Suggested Formula	Polyox™ WSR-301 5% Oral Adhesive Paste (Suspension, 100 g)	FIN	F 006 397
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Gelatin, NF	2.00	g				
Pectin (Pure, Citrus), USP	2.00	g				
Sodium Carboxymethylcellulose (Medium Viscosity), USP	4.00	g				
Xanthan Gum, NF	1.00	g				
Polyox™ WSR-301	5.00	g				
Medisca OleaBase™ Plasticized	86.00	g				





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible):

Polyox™ WSR-301, Sodium Carboxymethylcellulose

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).

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
Gelatin, NF	2.00	g			
Pectin (Pure, Citrus), USP	2.00	g			
Sodium Carboxymethylcellulose (Medium Viscosity), USP §	4.00	g			
Xanthan Gum, NF	1.00	g			
Polyox™ WSR-301 §	5.00	g			
Medisca OleaBase™ Plasticized	86.00	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Preparatory step:</u></p> <p>A. Prepare a hot water bath.</p> <p><u>Specifications:</u> Temperature: 40°C to 45°C.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. Pass the Polyox™ WSR-301 through a 40 or 50 mesh sieve (DO NOT TRITURATE) and weigh the required quantity.</p> <p><u>Note:</u> Do not use excessive force as Polyox™ WSR-301 should not be triturated.</p> <p>B. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> -Gelatin -Pectin (Pure, Citrus) -Sodium Carboxymethylcellulose (Medium Viscosity) -Xanthan Gum



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3.	<p><u>Medium preparation:</u></p> <p>A. Using the hot water bath, melt the OleaBase™ Plasticized.</p> <p><u>Specifications:</u> Maintain temperature between 40°C and 45°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p>IMPORTANT: Do not allow the temperature to exceed 45°C.</p>
4.	<p><u>Medium Integration:</u></p> <p>A. Using the hot water bath, sequentially add the following ingredients into the melted OleaBase™ Plasticized (Step 3A).</p> <p>-Fine, homogeneous powder blend (Step 2B) -Polyox™ WSR-301 (Step 2A)</p> <p><u>Specifications:</u> Continuously mix until homogeneous. Maintain temperature between 40°C and 45°C.</p> <p>B. Remove the mixture (Step 4A) from the heat. With continuous stirring, allow the mixture cool to room temperature.</p> <p><u>End result:</u> Homogeneous ointment-like dispersion.</p>
5.	<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	6 months, as per USP*.	Packaging Requirements	Tightly closed, light-resistant ointment tube/jar.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	Keep in a dry place.
	3	Protect from light.	7	Keep at room temperature (20°C – 23°C).
	4	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	
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>			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions. IMPORTANT: The quantity of API administered is directly dependent on the quantity of product applied.</p>			

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

REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 265.
2.	USP <795>. <i>United States Pharmacopeia XLI / National Formulary 36</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2018: 6546.

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