MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Acyclovir 5% Oral Adhesive Paste (Suspension, 60 g)	FIN	F 006 401

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acyclovir, USP	TBD					
Mineral Oil (Light), NF	3.0	mL				
Polyox™ WSR-301 Oral Adhesive Paste*	TBD					

*Formula # F 006 397 available on request.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Acyclovir, Mineral Oil (Light)*

Moisture sensitive *(protect from humidity whenever possible):* *Acyclovir*

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: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

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 60 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Acyclovir, USP §	TBD				
Mineral Oil (Light), NF	3.0	mL			
Polyox™ WSR-301 Oral Adhesive Paste	TBD				

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction

1. **Ingredient quantification:**

A. Determine the potency of Acyclovir based on the certificate of analysis:

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

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Acyclovir to make an Acyclovir 5 % Topical Cream, batch size (60 g):

Quantity of Acyclovir required for 60 g	3.000 g
DIVIDED BY	
Potency of Acyclovir (Step 1Ai)	_____
EQUALS	
i. Quantity of Acyclovir needed for 60 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Acyclovir needed *plus* processing error adjustments	_____ **g**

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3. **Ingredient quantification:**

A. Determine the actual quantity of Polyox Oral Adhesive Paste to weigh for the required batch size (60 g):

Total Weight of the batch	60.00 g
MINUS	
Total amount of other ingredient except Acyclovir	2.547 g
MINUS	
The weight of Acyclovir (Step 2Ai)	_____ g
EQUALS	
i. Quantity of Polyox Oral Adhesive Paste needed for 60 g	**_____ g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Weight of Polyox Oral Adhesive Paste required *plus* processing error adjustments	**_____ g**

4. **Powder-liquid preparation:**

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

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

End result: Homogeneous paste-like dispersion.

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

A. Incrementally add the homogeneous paste-like dispersion (Step 4B) to the Polyox Oral Adhesive Paste (amount determined in Step 3Aii).

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

End result: Homogeneous paste-like dispersion.

B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.

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6.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP*.		Packaging Requirements	- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.	
	2	Keep out of reach of children.	6	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.	7	Keep at room temperature (20°C – 23°C).	
	4	Protect from light.	8	May impair mental and/or physical ability. Use care when operating a car or machinery.	
Pharmacist Instructions	**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.** Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** 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

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5.	Acyclovir (Monograph). *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 2054.
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