



Suggested Formula	Acyclovir 200 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 141
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acyclovir, USP	TBD					
Propylene Glycol, USP	4.0	mL				
Tutti Frutti Flavor	1.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible): *Propylene Glycol*

**Light Sensitive** (protect from light whenever possible): *Acyclovir, Propylene Glycol*

**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 100 mL)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Acyclovir, USP §	TBD				
Propylene Glycol, USP §	4.0	mL			
Tutti Frutti Flavor	1.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL			

§ 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	_____
MULTIPLY BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
<b>i. Potency of Acyclovir, in decimal</b>	_____



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2.	<p><b><u>Ingredient quantification:</u></b></p> <p>A. Determine the quantity (in g) of Acyclovir required to make a 100 mL batch of Acyclovir 200 mg/5 mL Oral Liquid:</p> <table border="1" style="width: 100%;"><tr><td>Quantity Acyclovir required for a 100 mL Oral Liquid</td><td style="text-align: right;">4.000 g</td></tr><tr><td colspan="2">DIVIDED BY</td></tr><tr><td>Potency of Acyclovir, in decimal (Step 1Ai)</td><td style="text-align: right;">_____</td></tr><tr><td colspan="2">EQUALS</td></tr><tr><td><b>i. Quantity of Acyclovir needed for a 100 mL Oral Liquid</b></td><td style="text-align: right;">_____ g</td></tr><tr><td colspan="2">MULTIPLIED BY</td></tr><tr><td>Processing error adjustments (5 to 9%)</td><td style="text-align: right;">1.05 to 1.09</td></tr><tr><td colspan="2">EQUALS</td></tr><tr><td><b>ii. Quantity of Acyclovir needed <i>plus</i> processing error adjustments</b></td><td style="text-align: right;">_____ g</td></tr></table>	Quantity Acyclovir required for a 100 mL Oral Liquid	4.000 g	DIVIDED BY		Potency of Acyclovir, in decimal (Step 1Ai)	_____	EQUALS		<b>i. Quantity of Acyclovir needed for a 100 mL Oral Liquid</b>	_____ g	MULTIPLIED BY		Processing error adjustments (5 to 9%)	1.05 to 1.09	EQUALS		<b>ii. Quantity of Acyclovir needed <i>plus</i> processing error adjustments</b>	_____ g
Quantity Acyclovir required for a 100 mL Oral Liquid	4.000 g																		
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EQUALS																			
<b>ii. Quantity of Acyclovir needed <i>plus</i> processing error adjustments</b>	_____ g																		
3.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. Triturate the Acyclovir (amount determined from Step 2Aii) to form a fine, homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 3A) with the Propylene Glycol.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>																		
4.	<p><b><u>Medium integration:</u></b></p> <p>A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (50.0 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none"><li>-Tutti Frutti Flavor</li><li>-Homogeneous liquid-like dispersion (Step 3B)</li></ul> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p>																		



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5.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 4A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
6.	<p><b><u>Product transfer:</u></b></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>

**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date		Packaging Requirements	
14 days, refrigerated, as per USP.			- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 Cap tightly after use.
	2	Keep out of reach of children.	7 <b>Shake well before use.</b>
	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 Keep refrigerated. Do not freeze.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9 Protect from light.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	
Pharmacist Instructions	Add any auxiliary labels specific to the active to the dispensing container as deemed necessary.		
Patient Instructions	Contact your pharmacist in the event of adverse reactions.		



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## REFERENCES

1.	Suspensions. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 239.
2.	Zovirax Cream. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2014</i> : 3268.
3.	Propylene Glycol. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 672.
4.	Aciclovir. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 862.
5.	Acyclovir (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #134.
6.	Acyclovir. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 9.
7.	Acyclovir (Monograph). <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 1613.
8.	Acyclovir Systemic. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26<sup>th</sup> Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 29.
9.	USP <795>. <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.

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