MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
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technicalservices@medisca.net

Suggested Formula	Acyclovir 200 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 141v2

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				

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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: 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. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

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 (GFIs) 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 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	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	_____
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 required to make a 100 mL batch of Acyclovir 200 mg/5 mL Oral Liquid:

Quantity Acyclovir required for a 100 mL Oral Liquid	4.000 g
DIVIDED BY	
Potency of Acyclovir, in decimal (Step 1Ai)	_____
EQUALS	
i. Quantity of Acyclovir needed for a 100 mL Oral Liquid	_____ **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**

3. **Powder-liquid preparation:**

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

B. Levigate the fine, homogeneous powder (Step 3A) with the Propylene Glycol.

End result: Homogeneous liquid-like dispersion.

4. **Medium integration:**

A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (50.0 mL *plus* processing error adjustments):

-Tutti Frutti Flavor
-Homogeneous liquid-like dispersion (Step 3B)

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

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.

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

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP 795.		Packaging Requirements	- 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	**Shake well before 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.	8	Keep refrigerated (2°C – 8°C). 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

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