



MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

9/26/2020; Page 1

Suggested Formula	Acyclovir 400 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 004 361v3
-------------------	---	-----	-------------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acyclovir, USP	TBD					
Medisca CapsuBlend®-S	TBD					
Sodium Chloride, USP	As required					





Suggested Formula	Acyclovir 400 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 004 361v3
-------------------	---	-----	-------------

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible):	Acyclovir
Moisture Sensitive (protect from humidity whenever possible):	Acyclovir
Hygroscopic (protect from moisture whenever possible):	CapsuBlend®-S

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 (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.



Suggested Formula	Acyclovir 400 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 004 361v3
-------------------	---	-----	-------------

SUGGESTED PREPARATION (for 100 Size #0 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*):	Processing Error	Qty. to measure
Acyclovir, USP §	TBD				
Medisca CapsuBlend®-S §	TBD				
Sodium Chloride, USP	As required				

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

§ Weigh / measure just prior to use.

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	_____



Suggested Formula	Acyclovir 400 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 004 361v3
-------------------	---	-----	-------------

2.	<p><u>Ingredient quantification:</u></p> <p>A. Determine the quantity (in g) of Acyclovir required to make 100 capsules of Acyclovir 400 mg:</p> <table border="1" style="width: 100%;"> <tr> <td>Quantity of Acyclovir needed for each capsule</td> <td style="text-align: right;">0.400 g</td> </tr> <tr> <td>DIVIDED BY</td> <td></td> </tr> <tr> <td>Potency of Acyclovir, in decimal (Step 1Ai)</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>i. Actual Quantity of Acyclovir needed for each capsule</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>MULTIPLIED BY</td> <td></td> </tr> <tr> <td>Number of capsules</td> <td style="text-align: right;">100</td> </tr> <tr> <td>MULTIPLIED BY</td> <td></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>EQUALS</td> <td></td> </tr> <tr> <td>ii. Total Quantity of Acyclovir needed <i>plus</i> processing error adjustments</td> <td style="text-align: right;">_____ g</td> </tr> </table>	Quantity of Acyclovir needed for each capsule	0.400 g	DIVIDED BY		Potency of Acyclovir, in decimal (Step 1Ai)	_____	EQUALS		i. Actual Quantity of Acyclovir needed for each capsule	_____ g	MULTIPLIED BY		Number of capsules	100	MULTIPLIED BY		Processing error adjustments (5 to 9%)	1.05 to 1.09	EQUALS		ii. Total Quantity of Acyclovir needed <i>plus</i> processing error adjustments	_____ g
Quantity of Acyclovir needed for each capsule	0.400 g																						
DIVIDED BY																							
Potency of Acyclovir, in decimal (Step 1Ai)	_____																						
EQUALS																							
i. Actual Quantity of Acyclovir needed for each capsule	_____ g																						
MULTIPLIED BY																							
Number of capsules	100																						
MULTIPLIED BY																							
Processing error adjustments (5 to 9%)	1.05 to 1.09																						
EQUALS																							
ii. Total Quantity of Acyclovir needed <i>plus</i> processing error adjustments	_____ g																						
3.	<p><u>CapsuBlend®-S requirements for 100 x size #0 capsules</u></p> <p>A. Calculate the amount of CapsuBlend®-S required for the batch. Refer to attached appendix for details.</p>																						
4.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Acyclovir (amount determined in Step 2Aii) to form a fine, homogeneous powder.</p> <p>B. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none"> -Fine, homogeneous powder (Step 4A) -CapsuBlend®-S (amount determined in appendix, (I)) 																						



Suggested Formula	Acyclovir 400 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 004 361v3
5.	<u>Product transfer:</u> Fill each of 100 Size #0 capsules with the mixture (Step 4B). Close each capsule tightly. Clean each capsule by placing the capsules in a container filled with Sodium Chloride, and then gently rolling the container. Pour the container contents into a 10-mesh sieve, and allow the Sodium Chloride to pass through. Finally, roll the capsules on a cloth-covered surface.		
6.	<u>Validation technique (average capsule weight):</u> The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by adding Step 2Ai + the amount in appendix (G) together.		
7.	<u>Product transfer:</u> Transfer the final product into the specified dispensing container (see “Packaging Requirements”).		

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP 795*.	Packaging Requirements	Tightly closed, light-resistant capsule shells and vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep in a dry place.
	2	Keep out of reach of children.	7	Cap tightly after use.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep at controlled room temperature (20°C – 25°C).	9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Protect from light.		
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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



Suggested Formula	Acyclovir 400 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 004 361v3
-------------------	---	-----	-------------

REFERENCES

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 127.
2.	Zovirax Cream. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2010</i> . 2768.
3.	Sodium Chloride. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 6th Edition</i> . American Pharmaceutical Association; 2009: 637.
4.	Aciclovir. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 862.
5.	Acyclovir (Monograph). In: O'Neil MJ. <i>The Merck Index 14th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #146.
6.	Acyclovir (Monograph). <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 1427.
7.	Acyclovir Systemic. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 29.
8.	USP <795>. <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.

DISCLAIMER: THIS DOCUMENT IS COPYRIGHT© 2019-2020 MEDISCA PHARMACEUTIQUE INC. MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY, SCHEDULING OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW. MEDISCA NETWORK INC. MAKES NO WARRANTIES WITH RESPECT TO INFRINGEMENT OR NON-INFRINGEMENT BY THE FORMULA OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY OF ANY OTHER PARTY, AND IT IS THE RESPONSIBILITY OF THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO INVESTIGATE AND DETERMINE ANY SUCH ISSUE.



Appendix	Calculating the quantity of excipient required for the batch																						
Procedure																							
1.	<u>Capsule filling:</u> a. For <u>each</u> ingredient powder below, determine the average capsule fill weight by filling and weighing five TARED CAPSULES. Do not forget to divide the total weight by 5 to obtain an <u>average</u> capsule fill weight. Also, triturate the ingredient powder first if required in formulation. Plug each amount into Step 2, column B.																						
2.	<u>Volume Percent Occupied:</u> <table border="1"><thead><tr><th><u>Ingredients</u></th><th>Column A Quantity Required per capsule</th><th>Column B Average capsule fill weight</th><th>Column C A/B x 100 equals percent filled</th></tr></thead><tbody><tr><td>a. Acyclovir</td><td>_____</td><td>_____ g</td><td>_____ %</td></tr><tr><td colspan="4">Step 2Ai (Main Formula)</td></tr><tr><td>b. CapsuBlend®-S</td><td></td><td>_____ g</td><td></td></tr><tr><td>c. Total (add column C together)</td><td></td><td></td><td>_____ % (D)</td></tr></tbody></table>			<u>Ingredients</u>	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled	a. Acyclovir	_____	_____ g	_____ %	Step 2Ai (Main Formula)				b. CapsuBlend®-S		_____ g		c. Total (add column C together)			_____ % (D)
<u>Ingredients</u>	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled																				
a. Acyclovir	_____	_____ g	_____ %																				
Step 2Ai (Main Formula)																							
b. CapsuBlend®-S		_____ g																					
c. Total (add column C together)			_____ % (D)																				
3.	<u>Calculate the quantity of CapsuBlend®-S required for the batch:</u> a. Percent of CapsuBlend®-S required = 100% – (D) _____ % (E) b. Average capsule fill weight of CapsuBlend®-S (from column B, Step 2b): _____ g (F) c. Quantity of CapsuBlend®-S required per capsule = [(E) ÷ 100 × (F)] _____ g (G) d. Total quantity of CapsuBlend®-S required for the batch = 100 capsules × (G) _____ g (H) e. Total quantity of CapsuBlend®-S <i>plus</i> processing error = (H) x 1.05-1.09 _____ g (I)																						

DISCLAIMER: THIS DOCUMENT IS COPYRIGHT© 2019-2020 MEDISCA PHARMACEUTIQUE INC. MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY, SCHEDULING OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW. MEDISCA NETWORK INC. MAKES NO WARRANTIES WITH RESPECT TO INFRINGEMENT OR NON-INFRINGEMENT BY THE FORMULA OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY OF ANY OTHER PARTY, AND IT IS THE RESPONSIBILITY OF THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO INVESTIGATE AND DETERMINE ANY SUCH ISSUE.