



Suggested Formula	Sulfacetamide Sodium 10% Topical Foam (Solution, 50 mL)	FIN	F 006 817v2
-------------------	---	-----	-------------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Sulfacetamide Sodium, USP	TBD					
Medisca VersaPro™ Foam Base	q.s. to 50.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible):

Sulfacetamide Sodium, VersaPro™ Foam Base

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 **10 to 12%** 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.



Suggested Formula	Sulfacetamide Sodium 10% Topical Foam (Solution, 50 mL)	FIN	F 006 817v2
-------------------	---	-----	-------------

SUGGESTED PREPARATION (for 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Sulfacetamide Sodium, USP §	TBD				
Medisca VersaPro™ Foam Base §	q.s. to 50.0	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 Sulfacetamide Sodium based on the certificate of analysis:

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



Suggested Formula	Sulfacetamide Sodium 10% Topical Foam (Solution, 50 mL)	FIN	F 006 817v2
-------------------	---	-----	-------------

2.	<p><u>Ingredient quantification:</u></p> <p>A. Determine the quantity (in g) of Sulfacetamide Sodium required to make a Sulfacetamide Sodium 10% Topical Foam, batch size (50 mL):</p> <table border="1" style="width: 100%;"><tr><td>Quantity of Sulfacetamide Sodium required for 50 mL</td><td style="text-align: right;">5.000 g</td></tr><tr><td colspan="2">DIVIDED BY</td></tr><tr><td>Potency of Sulfacetamide Sodium, in decimal (Step 1Ai)</td><td style="text-align: right;">_____</td></tr><tr><td colspan="2">EQUALS</td></tr><tr><td>i. Quantity of Sulfacetamide Sodium needed for 50 mL</td><td style="text-align: right;">_____ g</td></tr><tr><td colspan="2">MULTIPLIED BY</td></tr><tr><td>Processing error adjustments (10 to 12%)</td><td style="text-align: right;">1.10 to 1.12</td></tr><tr><td colspan="2">EQUALS</td></tr><tr><td>ii. Quantity of Sulfacetamide Sodium needed <i>plus</i> processing error adjustments</td><td style="text-align: right;">_____ g</td></tr></table>	Quantity of Sulfacetamide Sodium required for 50 mL	5.000 g	DIVIDED BY		Potency of Sulfacetamide Sodium, in decimal (Step 1Ai)	_____	EQUALS		i. Quantity of Sulfacetamide Sodium needed for 50 mL	_____ g	MULTIPLIED BY		Processing error adjustments (10 to 12%)	1.10 to 1.12	EQUALS		ii. Quantity of Sulfacetamide Sodium needed <i>plus</i> processing error adjustments	_____ g
Quantity of Sulfacetamide Sodium required for 50 mL	5.000 g																		
DIVIDED BY																			
Potency of Sulfacetamide Sodium, in decimal (Step 1Ai)	_____																		
EQUALS																			
i. Quantity of Sulfacetamide Sodium needed for 50 mL	_____ g																		
MULTIPLIED BY																			
Processing error adjustments (10 to 12%)	1.10 to 1.12																		
EQUALS																			
ii. Quantity of Sulfacetamide Sodium needed <i>plus</i> processing error adjustments	_____ g																		
3.	<p><u>Filling to volume:</u></p> <p>A. Incrementally add the VersaPro™ Foam Base to the Sulfacetamide Sodium (amount determined in Step 2Aii) to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>																		
4.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>																		



Suggested Formula	Sulfacetamide Sodium 10% Topical Foam (Solution, 50 mL)	FIN	F 006 817v2
-------------------	---	-----	-------------

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	30 days, as per USP.		Packaging Requirements	- Tightly closed, light-resistant topical dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	Protect from light.
	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	For external use only.
	4	Keep at room temperature (20°C – 23°C).		
Pharmacist Instructions	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.			

REFERENCES

1.	Cosmetics for special populations and for use as vehicles. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 441.
2.	Sulfacetamide Sodium. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 335.
3.	Sulfacetamide Sodium (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #9031.
4.	Sulfacetamide Sodium. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 450.
5.	Sulfacetamide Sodium (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 5933.
6.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

DISCLAIMER: 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 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. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST 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 TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.