MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Misoprostol 0.0024%, Nifedipine 2%, Phenytoin Sodium 5% Topical Ointment (Suspension, 60 g)	FIN	F 006 361

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Misoprostol 1% Dispersion, USP	0.144	g				
Nifedipine, USP	1.200	g				
Phenytoin Sodium, USP	3.000	g				
Polyethylene Glycol 300, NF	5.40	mL				
Medisca AlpaWash™	49.61	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Nifedipine*

Narrow Therapeutic Index *Phenytoin Sodium*

Hygroscopic *(protect from moisture whenever possible):* *Misoprostol, Phenytoin Sodium, Polyethylene Glycol 300*

Air sensitive *(protect from air whenever possible):* *Phenytoin Sodium*

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.

Phenytoin Sodium has a Narrow Therapeutic Index.

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
Misoprostol 1% Dispersion, USP §	0.144	g			
Nifedipine, USP §	1.200	g			
Phenytoin Sodium, USP §	3.000	g			
Polyethylene Glycol 300, NF §	5.40	mL			
Medisca AlpaWash™	49.61	g			

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

Preparatory Instruction	
1.	**Powder-liquid preparation:** A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Misoprostol 1% Dispersion -Nifedipine -Phenytoin Sodium B. Levigate the homogeneous powder blend (Step 1A) with the Polyethylene Glycol 300. End result: Homogeneous liquid-like dispersion.
2.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the AlpaWash™. Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion. B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
3.	**Product transfer:** Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP*.		Packaging Requirements	- Tightly closed, light-resistant container. - To be administered with a metered-dose measuring device.
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	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	For external use only.	
	4	Keep at room temperature (20°C – 23°C).	9	Protect from light.	
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	10	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	
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. **IMPORTANT: DRUG-DRUG INTERACTION EXISTS BETWEEN NIFEDIPINE AND PHENYTOIN SODIUM. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.**				
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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