MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Nifedipine 32.5 mg Rectal Suppositories (Solid Suspension, 30 × 7.0 mL Suppositories)	FIN	F 005 869

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Nifedipine, USP	0.975	g				
Silica Gel (Micronized)	0.75	g				
Medisca SPG Supposi-Base™	189.06	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Hygroscopic *(protect from moisture whenever possible):* *Silica Gel*

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 30 x 7.0 mL Suppositories)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Nifedipine, USP §	0.975	g			
Silica Gel (Micronized) §	0.75	g			
Medisca SPG Supposi-Base™	189.06	g			

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

Preparatory Instruction	
1.	**Preparatory step:** A. Prepare a hot water bath. Specifications: Temperature: 40 to 45°C.
2.	**Mold lubrication:** A. Lubricate all parts of the suppository mold with suitable vegetable spray and set aside. Note: Selected vegetable spray needs to be compatible with API(s) and all other ingredients within the formulation.
3.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Nifedipine -Silica Gel (Micronized)
4.	**Medium preparation:** A. Using the hot water bath, melt the SPG Supposi-Base™. Specifications: Maintain temperature between 40°C and 45°C. End result: Homogeneous liquid-like solution. IMPORTANT: Do not allow the temperature to exceed 45°C.

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5. **Medium integration:**

A. Using the hot water bath, incrementally add the fine, homogeneous powder blend (Step 3A) to the melted SPG Supposi-Base™ (Step 4A).

Specifications: Continuously mix, using high-shear mixing techniques.
Maintain temperature between 40°C and 45°C.

End result: Homogeneous liquid-like dispersion.

6. **Mold filling:**

A. Remove the mixture (Step 5A) from the heat. With continuous stirring, allow to cool slightly, until the mixture is thicker (with a lotion-like consistency).

B. Fill the 30 mold cavities with the mixture. If the mixture starts to solidify, reheat to 40 – 45°C, and repeat the filling procedure.

C. Once the cavities have been filled, allow the suppositories to cool to room temperature.

D. If necessary, trim the tops of the suppositories with a sharp blade or a hot spatula.

7. **Validation technique:**

A. Weigh 6 suppositories separately.

B. The final weight of each suppository from Step 7A (not including the weight of the suppository mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 6.36 g in accordance to USP guidelines.

8. **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, refrigerated, as per USP*.	Packaging Requirements		Individually wrapped in foil and placed in a tightly closed, light-resistant suppository box or wide-mouth container.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	8		Equilibrate to room temperature before use.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	9		Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Protect from light.	10		Cap tightly after use.
	5	Keep in a dry place.	11		For rectal use only.
	6	Keep refrigerated. Do not freeze.			
Pharmacist Instructions		Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.			
Patient Instructions		If allergic reactions occur, consult your pharmacist.			

*** 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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REFERENCES

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