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

Suggested Formula	Hydrocortisone 90 mg Mucoadhesive Rectal Suppositories (Solid Suspension, 30 × 1.4 g [1.362 mL] Suppositories)	FIN	F 008 455

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydrocortisone (Micronized), USP	2.700	g				
Polysorbate 80, NF	1.5	mL				
Medisca NovaFilm™ Gel Base	15.0	mL				
Medisca SPG Supposi-Base™	20.47	g				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Hydrocortisone, NovaFilm™ Gel Base*

Oxygen Sensitive *(protect from oxygen whenever possible):* *Polysorbate 80*

Hygroscopic *(protect from moisture whenever possible):* *Polysorbate 80*

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 **12 to 15%** 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 30 x 1.4 g [1.362 mL])

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Hydrocortisone (Micronized), USP §	2.700	g			
Polysorbate 80, NF §	1.5	mL			
Medisca NovaFilm™ Gel Base §	15.0	mL			
Medisca SPG Supposi-Base™	20.47	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.	**Powder-liquid preparation**: A. Combine and mix the following ingredients together to form a homogeneous liquid-like dispersion: -NovaFilm™ Gel Base -Polysorbate 80 B Levigate the Hydrocortisone (Micronized) with the homogeneous liquid-like dispersion (Step 2A). End result: Homogeneous paste-like dispersion.
3.	**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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4.	**Medium integration:** A. Using the hot water bath, incrementally add the homogeneous paste-like dispersion (Step 2B) into the melted SPG Supposi-Base™ (Step 3A). Specifications: Continuously mix, using high-shear mixing techniques. Maintain temperature between 40°C and 45°C. End result: Homogeneous liquid-like dispersion.
5.	**Mold filling:** A. Remove the homogeneous liquid-like dispersion (Step 4A) 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. Note: Continuously mix during the transfer process in order to maintain homogeneity. C. Once the molds 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.
6.	**Validation technique:** A. Weigh 6 suppositories separately. B. The final weight of each suppository from Step 6A (not including the weight of the suppository shell) shall not be less than 90% and not more than 110% of the theoretically calculated weight 1.35 g in accordance to USP guidelines.
7.	**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 a 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.	6	Keep in a dry place.	
	2	Keep out of reach of children.	7	Equilibrate to room temperature 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	May impair mental and/or physical ability. Use care when operating a car or machinery.	
	5	Protect from light.	10	For rectal use only.	
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

1. Suppositories and Insert. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 231.
2. Hydrocortisone. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1535.
3. Hydrocortisone (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4824.
4. Hydrocortisone. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 241.
5. Hydrocortisone (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2180.
6. USP <795>. *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6951.