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	Betamethasone 0.05% Topical Gel (Suspension, 100 g)	FIN	F 002 911v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Betamethasone 17, 21 Dipropionate, USP*	0.064	g				
Propylene Glycol, USP	0.5	mL				
Medisca HRT Gel Base	99.42	g				

*Betamethasone Dipropionate 0.064 g is equivalent to Betamethasone 0.050 g.

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	Betamethasone 0.05% Topical Gel (Suspension, 100 g)	FIN	F 002 911v2

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Betamethasone 17, 21 Dipropionate Propylene Glycol*

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol*

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 (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.

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	Betamethasone 0.05% Topical Gel (Suspension, 100 g)	FIN	F 002 911v2

SUGGESTED PREPARATION (for 100 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Betamethasone 17, 21 Dipropionate, USP §	0.064	g			
Propylene Glycol, USP §	0.5	mL			
Medisca HRT Gel Base	99.42	g			

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

Preparatory Instruction	
1.	**Powder-Liquid preparation:** A. Levigate the Betamethasone 17, 21 Dipropionate with the Propylene Glycol. End result: Homogeneous liquid-like dispersion.
2.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1A) to the HRT Gel Base. Specifications: Continuously mix. End result: Homogeneous gel-like dispersion.
3.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

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	Betamethasone 0.05% Topical Gel (Suspension, 100 g)	FIN	F 002 911v2

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		35 days, controlled room temperature or refrigerator, as per USP 795*.	Packaging Requirements		Tightly closed, light-resistant ointment tube or jar.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		5	Cap tightly after use.
	2	Keep out of reach of children.		6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Keep in a dry place.		7	For external use only.
	4	Keep at controlled room temperature (20°C – 25°C) OR keep refrigerated (2°C – 8°C). Do not freeze.		8	Protect from light.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT:** - Small batch is prepared due to inherent potential of systemic toxicity. - Limits as to the total amount of product used should be established by a physician. - You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas. - Continued application of this product might produce systemic side effects. Advise patient accordingly.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** - Do not cover the site of application. - The quantity of API administered is directly dependent on the quantity of product applied.				

*** If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.**

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	Betamethasone 0.05% Topical Gel (Suspension, 100 g)	FIN	F 002 911v2

REFERENCES

1. Propylene Glycol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 521.
2. Betamethasone (micronized) (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #1180.
3. Betamethasone Dipropionate (micronized) (Monograph). *United States Pharmacopeia XXVIII / National Formulary 23*. Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 246.
4. USP <795>. *United States Pharmacopeia XXVIII / National Formulary 23*. Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
5. Betamethasone (micronized). *USP DI – Drug Information for the Health Care Professional, 26th Edition*. Thomson Micromedex.; Greenwood Village, CO: 2006: 990.