MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Buprenorphine 0.05 mg Oral Transmucosal Films (Solid Suspension, 30 Films)	FIN	F 009 911

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Buprenorphine 1% Stock Solution †	0.15	mL				
Bitterness Reducing Agent (NF-01) (Natural) (Powder)	0.25	g				
Colloidal Silicon Dioxide, NF	1.145	g				
Chicken (Powder)	0.06	g				
Sucralose, NF	0.045	g				
Glycerin, USP	0.06	g				
Purified Water, USP	8.0	mL				
NovaFilm™ Gel Base	18.00	g				
Purified Water, USP	q.s. to 30.0	mL				
† **Buprenorphine 1% Stock Solution**						
Buprenorphine Hydrochloride, USP*	0.108					
Purified Water, USP	9.0	mL				
Purified Water, USP	q.s. to 10.0	mL				

* Buprenorphine Hydrochloride 0.108 g is equivalent to Buprenorphine 0.100 g.

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Colloidal Silicon Dioxide, Glycerin, Buprenorphine Hydrochloride*

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

Controlled Substance *(adhere to proper handling and documentation procedures)* *Buprenorphine Hydrochloride*

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 Films)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Buprenorphine 1% Stock Solution † §	0.15	mL			
Bitterness Reducing Agent (NF-01) (Natural) (Powder)	0.25	g			
Colloidal Silicon Dioxide, NF §	1.145	g			
Chicken (Powder)	0.06	g			
Sucralose, NF	0.045	g			
Glycerin, USP §	0.06	g			
Purified Water, USP	8.0	mL			
NovaFilm™ Gel Base §	18.00	g			
Purified Water, USP	q.s. to 30.0	mL			
† **Buprenorphine 1% Stock Solution**					
Buprenorphine Hydrochloride, USP §	0.108				
Purified Water, USP	9.0	mL			
Purified Water, USP	q.s. to 10.0	mL			

Preparatory Instruction

1. † **Buprenorphine 1% Stock Solution Preparation:**

   A. Triturate the Buprenorphine Hydrochloride (0.108 g) to form a fine, homogeneous powder.

   B. Incrementally add the fine, homogeneous powder (Step 1A) to the Purified Water (9.0 mL).

   Specifications: Continuously mix until all solid particles have completely dissolved.

   End result: Homogeneous liquid-like solution.

   C. Add additional Purified Water to the mixture (Step 1B) to fill to the required batch size (10.0 mL).

   Specifications: Continuously mix.

   End result: Homogeneous liquid-like solution.

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2. **Powder-liquid preparation:**

A. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Bitterness Reducing Agent (NF-01) (Natural) (Powder)
-Colloidal Silicon Dioxide, NF
-Chicken (Powder)
-Sucralose

B. Levigate the fine, homogeneous powder blend (Step 2A) with the Buprenorphine 1% Stock Solution (0.15 mL *plus* processing error adjustments), Purified Water (8.0 mL *plus* processing error adjustments) and Glycerin.

End result: Homogeneous liquid-like dispersion.

3. **Medium incorporation:**

A. Incrementally add the homogeneous liquid-like dispersion (Step 2B) to the NovaFilm™ Gel Base.

Specifications: Continuously mix, using high-shear mixing techniques.

NOTE: Ensure mixing process does not incorporate any air.

End result: Homogeneous gel-like dispersion.

4. **Filling to volume:**

A. Add additional Purified Water to the mixture (Step 3A) to fill to the required batch size (30.0 mL *plus* processing error adjustments).

Specifications: Continuously mix, using high-shear mixing techniques.

NOTE: Ensure mixing process does not incorporate any air.

End result: Homogeneous gel-like dispersion.

5. **Mold filling and heating:**

A. Fill the 30 blister mold cavities with 1.00 mL of the homogeneous gel-like dispersion (Step 4A) per cavity. Spread the homogeneous gel-like dispersion in the cavity to a uniform thickness.

NOTE: Ensure no air bubbles are added to the mold cavities.

B. Heat the filled blister molds to 50°C for 60 to 90 minutes in the preheated convection oven. Do not overheat.

Specifications: Homogeneous solid dispersion.

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6.	**Cooling:** A. Carefully remove the blister mold from the heated oven. B. Allow the films to cool for an additional 15- 30 minutes in the blister molds. At controlled temperature and relative humidity.
7.	**Validation technique:** A. Weigh 6 films separately. B. The final weight of each film from Step 7A (not including the weight of the blister mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 0.159 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		180 days, controlled room temperature or refrigerator, as per USP 795*.	Packaging Requirements		Manually lock blister molds and put into light-resistant resealable foil pouch.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Discard container after use.
	2	Keep out of reach of children.	8		Keep at controlled room temperature (20°C – 25°C) OR keep refrigerated (2°C – 8°C). Do not freeze.
	3	Keep in a dry place.	9		Protect from light.
	4	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	10		For veterinary use only.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	11		May produce psychological and/or physical dependence.
	6	May impair mental and/or physical ability.	12		Controlled substance. Dangerous unless used as directed.
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.			

*** 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.**

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REFERENCES

1. Lozenge, Troches, and Films. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 215.
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9. USP <795>. *United States Pharmacopeia / National Formulary.* Rockville, MD. US Pharmacopeial Convention, Inc. 2023.