MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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technicalservices@medisca.net

Suggested Formula	Nystatin 100,000 IU/mL Oral Liquid (Suspension, 100 mL)	FIN	F 008 098

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Nystatin, USP	10	MU				
Propylene Glycol, USP	7.0	mL				
Methylcellulose Gel (1%)	50.0	mL				
Methylcellulose Gel (1%)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					
Citric Acid 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Propylene Glycol, Nystatin*

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

Oxygen Sensitive *(protect from oxygen whenever possible):* *Nystatin*

Moisture Sensitive *(protect from humidity whenever possible):* *Nystatin, Citric Acid*

Air Sensitive *(protect from air whenever possible):* *Nystatin*

Heat Sensitive *(protect from heat whenever possible):* *Nystatin*

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing 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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Nystatin, USP §	10	MU			
Propylene Glycol, USP §	7.0	mL			
Methylcellulose Gel (1%)	50.0	mL			
Methylcellulose Gel (1%)	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				
Citric Acid 10% Solution	As required				

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

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Preparatory Instruction

1. **Ingredient quantification:**

A. Determine the quantity (in g) of Nystatin required to make a Nystatin 10 MU Oral Liquid, batch size (100 mL):

Quantity of Nystatin (in Units) required	10,000,000 IU
DIVIDED BY	
Nystatin biopotency assay result (from Certificate of Analysis)	_____ IU/mg
EQUALS	
i. Quantity of Nystatin (in milligrams) required	_____ mg
MULTIPLIED BY	
Multiplication factor – milligrams to grams	0.001
EQUALS	
ii. Quantity of Nystatin (in grams) required	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
iii. Quantity of Nystatin needed *plus* processing error adjustments	_____ **g**

2. **Powder-liquid preparation:**

A. Triturate the Nystatin (Amount determined in Step 1Aiii) to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 2A) with the Propylene Glycol.

End result: Homogeneous liquid-like dispersion.

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3. **Medium integration:**

A. Incrementally add the following ingredients to the Methylcellulose Gel (1%) (50.0 mL *plus* processing error adjustments):

-Homogeneous liquid-like dispersion (Step 2B)

Specifications: Continuously mix.

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.

4. **Filling to volume:**

A. Add additional Methylcellulose Gel (1%) to the homogeneous liquid-like dispersion (Step 3A) to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specifications: Continuously mix until homogeneous.

End result: Homogeneous liquid-like dispersion.

5. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 4A).

B. Test the pH of the sample. It should lie between 6.0 and 7.0.

C. If the pH < 6.0, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 6.0 to 7.0 is obtained.

IMPORTANT: Do not allow the pH to rise above 7.0.

D. If the pH > 7.0, carefully add, in a dropwise fashion, the Citric Acid 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Citric Acid 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Citric Acid 10% Solution.
3. Re-test the pH.
4. Continue to add the Citric Acid 10% Solution until the pH of 6.0 to 7.0 is obtained.

IMPORTANT: Do not allow the pH to fall below 6.0.

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6.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements"). Note: Continuously mix the final product during the transfer process in order to maintain homogeneity.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		**7 days**, refrigerated, as per USP.	Packaging Requirements		- Tightly closed, light resistant dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		5	Keep out of reach of children.
	2	Protect from light.		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	**Shake well before use.**		7	Cap tightly after use.
	4	Keep refrigerated. Do not freeze.			
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.			

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REFERENCES

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