MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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technicalservices@medisca.net

Suggested Formula	Acetylcysteine 200 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 007 673v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acetylcysteine (N-Acetyl-L-Cysteine), USP	20.000	g				
Sodium Hydroxide, NF	2.45	g				
Edetate Disodium, USP	0.05	g				
Stevia Powder	0.15	g				
Raspberry Flavor	2.0	mL				
Purified Water, USP	60.0	mL				
Purified Water, USP	10.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Stevia Powder, Edetate Disodium*

Light Sensitive *(protect from light whenever possible):* *Acetylcysteine*

Corrosive Material *(causes burns to every area of contact):* *Sodium Hydroxide*

Metal Reactive *(protect from metals whenever possible):* *Acetylcysteine*

Oxygen Sensitive *(protect from air whenever possible):* *Acetylcysteine*

Rubber Reactive *(do not allow to come into contact):* *Acetylcysteine*

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors 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
Acetylcysteine (N-Acetyl-L-Cysteine), USP §	20.000	g			
Sodium Hydroxide, NF §	2.45	g			
Edetate Disodium, USP §	0.05	g			
Stevia Powder §	0.15	g			
Raspberry Flavor	2.0	mL			
Purified Water, USP	60.0	mL			
Purified Water, USP	10.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				

* 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. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Edetate Disodium -Purified Water (60.0 mL *plus* processing error adjustments). B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Sodium Hydroxide -Purified Water (10.0 mL *plus* processing error adjustments).

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2. **Medium incorporation:**

A. In the given, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 1A):

-Acetylcysteine (N-Acetyl-L-Cysteine)
-Homogeneous liquid-like solution (Step 1B)
-Stevia Powder
-Raspberry Flavor

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

End result: Homogeneous liquid-like solution.

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

3. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 2A).

B. Test the pH of the sample. It should lie between 3.5 and 4.0.

C. If the pH < 3.5, 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 3.5 to 4.0 is obtained.

IMPORTANT: Do not allow the pH to rise above 4.0.

4. **Filling to volume:**

A. Add additionnal Purified Water to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

5. **Product transfer:**

Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 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	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	6	Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Protect from light.	8	May impair mental and/or physical ability. Use care when operating a car or machinery.
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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