MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Lithium Citrate 1.6 mEq/mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 701v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lithium Citrate, USP	TBD					
Stevia Powder	0.20	g				
Tutti Frutti Flavor	0.5	mL				
Glycerin, USP	5.0	mL				
Medisca Oral Syrup SF (Sugar-Free Flavored Syrup Vehicle)	50.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

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
Lithium Citrate, USP	TBD				
Stevia Powder §	0.20	g			
Tutti Frutti Flavor	0.5	mL			
Glycerin, USP §	5.0	mL			
Medisca Oral Syrup SF (Sugar-Free Flavored Syrup Vehicle)	50.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	q.s. to 100.0	mL			

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

Preparatory Instruction

1. **Ingredient quantification:**

A. Determine the potency of Lithium Citrate based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Lithium Citrate, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Lithium Citrate, in decimal	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Lithium Citrate required to make 100 mL of Lithium Citrate 1.6 mEq/mL:

Quantity of Lithium Citrate needed for the batch	11.196 g
DIVIDED BY	
Potency of Lithium Citrate, in decimal (Step 1Ai)	_____
EQUALS	
i. Actual Quantity of Lithium Citrate needed for the batch	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
ii. Total Quantity of Lithium Citrate needed *plus* processing error adjustments	_____ **g**

3. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Lithium Citrate (amount determined in Step 2Aii)
-Stevia Powder

B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution:

-Glycerin
-Tutti Frutti Flavor

C. Levigate the fine, homogeneous powder blend (Step 3A) with the homogeneous liquid-like solution (Step 3B).

End result: Homogeneous paste-like dispersion.

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4.	**Medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 3C) to the Oral Syrup SF (Sugar-Free Flavored Syrup Vehicle). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
5.	**Filling to volume:** A. Add Oral Suspend (Suspending Vehicle) to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
6.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements		Tightly closed, prescription bottle with a metered-dose measuring device
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	7		Cap tightly after use.
	3	**Shake well before use.**	8		Keep refrigerated. Do not freeze.
	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.	9		Do not give to children under 12 years of age as the safety and effectiveness have not yet been established.
	5	**Important: Do not give to pregnant women or a nursing mother.**	10		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

1.	Suspension. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 239.
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