

TELEPHONE: 514-905-5096 FAX: 514-905-5097 technicalservices@medisca.net

11/7/2016; Page 1

Suggested Formula Lithium Citrate 1.6 mEq/mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 701v3
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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

<u>Ingredient-Specific Information</u>	
Hygroscopic (protect from moi	sture whenever possible): Glycerin, Stevia Powder
Suggested Preparatory Guidelines	
Non-Sterile Preparat	ion Sterile Preparation
<u>Processing Error /</u> <u>Testing Considerations</u> :	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.



TELEPHONE: 514-905-5096 FAX: 514-905-5097 technicalservices@medisca.net

11/7/2016; Page 2

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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	1		
Medisca Oral Suspend (Suspending Vehicle)	q.s. to 100.0	mL	1		

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

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



MEDISCA® NETWORK INC. TECHNICAL SUPPORT SERVICES FORMULATION CHEMISTRY DEPARTMENT

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11/7/2016; Page 3

Sug F	ggeste ormul	Lithium Citrate 1.6 mEq/mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 701v3
2.	Ing	redient quantification:		
	A.	Determine the quantity (in g) of Lithium Citrate required to make 100 mL of Lithium Citrate required to make 10	rate 1.6	5 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	1.05 to 1.09
		EQUALS		
		ii. Total Quantity of Lithium Citrate needed plus processing error adjustments	-	g
	L			
3.		wder-liquid preparation:		
	A.	Combine and triturate the following ingredients together to form a fine, homogeneous pov	wder b	lend:
		-Lithium Citrate (amount determined in Step 2Aii) -Stevia Powder		
	B.	Combine and mix the following ingredients together to form a homogeneous liquid-like s	olutior	n:
		-Glycerin -Tutti Frutti Flavor		
	C.	Levigate the fine, homogeneous powder blend (Step 3A) with the homogeneous liquid-like	ce solu	tion (Step 3B).
		End result: Homogeneous paste-like dispersion.		



TELEPHONE: 514-905-5096 FAX: 514-905-5097 technicalservices@medisca.net

11/7/2016; Page 4

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Formula	Lithium Citrate 1.6 mEq/mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 701v3

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 USP. Package Requireme			Tightly closed, prescription bottle with a metered-dose measuring device		
	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.	out of reach of children.		Cap tightly after use.
Auxiliary	3	Shake well before use.		8	Keep refrigerated. Do not freeze.
Labels	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. Important: Do not give to pregnant women or a nursing mother.		9	Do not give to children under 12 years of age as the safety and effectiveness have not yet been established.
	5			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				nsing container as deemed necessary.
Patient Instructions	Contact your pharmacist in the event of adverse reactions			ns.	



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11/7/2016; Page 5

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