MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Cephalexin 250 mg /5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 000 340v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Cephalexin (Monohydrate), USP	TBD					
Methylparaben, NF	0.10	g				
Hypromellose (4000 CPS) (Methocel E4M), USP	0.50	g				
Propylene glycol, USP	8.0	mL				
Orange Flavor	1.0	mL				
Sorbitol Solution (70%), USP	20.0	mL				
Purified Water, USP	60.0	mL				
Purified Water, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Cephalexin, Propylene glycol*

Hygroscopic *(protect from moisture whenever possible):* *Cephalexin, Propylene glycol, Hypromellose, Sorbitol Solution*

Plastic reactive / adsorbent *(do not allow to come into contact):* *Methylparaben*

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

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
Cephalexin (Monohydrate), USP §	TBD				
Methylparaben, NF §	0.10	g			
Hypromellose (4000 CPS) (Methocel E4M), USP §	0.50	g			
Propylene glycol, USP §	8.0	mL			
Orange Flavor	1.0	mL			
Sorbitol Solution (70%), USP §	20.0	mL			
Purified Water, USP	60.0	mL			
Purified Water, USP	q.s. to 100.0	mL			

* 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 potency of Cephalexin (Monohydrate) based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Cephalexin (Monohydrate), in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ µg/mg
MULTIPLIED BY (Multiplication factor – µg to grams /mg to grams)	0.001
EQUALS	
i. Potency of Cephalexin (Monohydrate) in g/g	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Cephalexin (Monohydrate) to make a 100 mL batch of Cephalexin 250 mg/5 mL Oral Liquid:

Quantity of Cephalexin required for 100 mL	5.000
DIVIDED BY	
Potency of Cephalexin (Monohydrate), in decimal (Step 1Ai)	_____
EQUALS	
i. Quantity of Cephalexin (Monohydrate) needed for 100 mL	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
ii. Quantity of Cephalexin (Monohydrate) 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:

-Cephalexin (Monohydrate) (amount determined in step 2Aii)
-Methylparaben
-Hypromellose (4000 CPS) (Methocel E4M)

B. Levigate the fine, homogeneous powder blend (Step 3A) with the Propylene glycol.

End result: Homogeneous paste-like dispersion.

4. **Liquid preparation:**

A. Incrementally add the following ingredients to the Purified Water (60.0 mL *plus* processing error adjustments):

-Sorbitol Solution (70%)
-Orange Flavor

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

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5.	**Powder-Liquid integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 3B) to the homogeneous liquid-like solution (Step 4A). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
6.	**Filling to volume:** A. Add additional Purified Water to the homogeneous liquid-like dispersion (Step 5A) 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.
7.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements"). Note: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements		Tightly closed, light-resistant glass prescription bottle with 5 mL dosing syringe.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Cap tightly after use.
	2	Keep out of reach of children.		7	**Shake well before use.**
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.		8	Do not use if irreversible caking or sedimentation occurs.
	4	Keep refrigerated. Do not freeze		9	Protect from light.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		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	If allergic reactions occur, consult your pharmacist.				

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REFERENCES

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