MEDISCA® NETWORK INC.
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Suggested Formula	Erythromycin Ethylsuccinate 46.8 mg/mL Oral Liquid (Suspension, 120 mL)	FIN	F 004 001

Note: Erythromycin Ethylsuccinate 46.8 mg/mL is equivalent to Erythromycin 40 mg/mL

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Erythromycin Ethylsuccinate, USP	5.616	g				
Sodium Citrate, USP	3.00	g				
Simethicone, USP	3.0	mL				
Carboxymethylcellulose Sodium 1.5% solution †	25.0	mL				
Xanthan Gum, NF	0.30	g				
Saccharin Sodium, USP	0.06	g				
Cherry Flavor	0.4	mL				
Potassium Sorbate, NF	0.24	g				
Purified Water, USP	10.0	mL				
Syrup (simple), NF	50.0	mL				
Syrup (simple), NF	q.s. to 120.0	mL				
Sodium Hydroxide 10% solution	As required					
† **Carboxymethylcellulose Sodium 1.5% solution**						
Carboxymethylcellulose Sodium, USP	0.75	g				
Purified Water, USP	40.0	mL				
Purified Water, USP	q.s. to 50.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):*	*Potassium Sorbate*
Hygroscopic *(protect from moisture whenever possible):*	*Erythromycin Ethylsuccinate, Carboxymethylcellulose Sodium*

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 120 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Erythromycin Ethylsuccinate, USP §	5.616	g			
Sodium Citrate, USP	3.00	g			
Simethicone, USP	3.0	mL			
Carboxymethylcellulose Sodium 1.5% solution † §	25.0	mL			
Xanthan Gum, NF	0.30	g			
Saccharin Sodium, USP	0.06	g			
Cherry Flavor	0.4	mL			
Potassium Sorbate, NF §	0.24	g			
Purified Water, USP	10.0	mL			
Syrup (simple), NF	50.0	mL			
Syrup (simple), NF	q.s. to 120.0	mL			
Sodium Hydroxide 10% solution	As required				
† **Carboxymethylcellulose Sodium 1.5% solution**					
Carboxymethylcellulose Sodium, USP §	0.75	g	--	--	
Purified Water, USP	40.0	mL	--	--	
Purified Water, USP	q.s. to 50.0	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.	† **Carboxymethylcellulose Sodium 1.5% solution preparation:** A. Incrementally add the Carboxymethylcellulose Sodium to the Purified Water (40.0 mL). Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution. B. Add additional Purified Water to the mixture (Step 1A) to fill to the required batch size (50.0 mL). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
2.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Erythromycin Ethylsuccinate -Xanthan Gum -Simethicone B. In the given order, sequentially add the following ingredients to the Carboxymethylcellulose Sodium 1.5% (25.0 mL *plus* processing error adjustments) -fine, homogeneous powder blend (Step 2A) -Syrup (simple) (50.0 mL *plus* processing error adjustments) Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion. Note: Add the next ingredient, once the previous one has been completely added and dispersed.

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3. **Medium preparation:**

A. Incrementally add the following ingredients to the Purified Water (10.0 mL *plus* processing error adjustments):

-Potassium Sorbate
-Saccharin Sodium
-Sodium Citrate

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

End result: Homogeneous liquid-like solution.

B. In the given order, sequentially add the following ingredients to the homogeneous liquid-like dispersion (Step 2B):

-Homogeneous liquid-like solution (Step 3A)
-Cherry Flavor

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous liquid-like dispesion.

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

4. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 3B).

B. Test the pH of the sample. It should lie between 6.5 and 8.5.

C. If the pH < 6.5, carefully add in a dropwise manner 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 6.5 to 8.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 8.5

5. **Filling to volume:**

A. Add additional Syrup (Simple) to the above mixture to fill to the required batch size (120.0 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").

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	35 days, refrigerated.		Packaging Requirements	- Tight, 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	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.	6	Shake well before use.
	3	Keep in a dry place.	7	Cap tightly after use.
	4	Keep refrigerated. Do not freeze.	8	Protect from light.
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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