MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Azithromycin 200 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 142v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Azithromycin (Dihydrate), USP	TBD					
Glycerin, USP	20.0	mL				
Cherry Flavor (Artificial)	0.3	mL				
Banana Cream Flavor	0.5	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	35.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Glycerin*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing 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
Azithromycin (Dihydrate), USP	TBD				
Glycerin, USP §	20.0	mL			
Cherry Flavor (Artificial)	0.3	mL			
Banana Cream Flavor	0.5	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	35.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				
Hydrochloric Acid 10% Solution	As required				

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

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Preparatory Instruction

1. **Ingredient quantification:**

A. Determine the potency of Azithromycin (Dihydrate) based on the certificate of analysis:

	100%
MINUS	
Water content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Azithromycin (Dihydrate), 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 Azithromycin (Dihydrate) in g/g	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Azithromycin (Dihydrate) required to make a 100 mL batch of Azithromycin 200 mg/5 mL Oral Liquid:

Quantity of Azithromycin (Dihydrate) required for 100 mL	4.000 g
DIVIDED BY	
Potency of Azithromycin (Dihydrate) in g/g (Step 1Ai)	_____
EQUALS	
i. Quantity of Azithromycin (Dihydrate) needed for 100 mL	_____ **g**
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Azithromycin (Dihydrate) needed *plus* processing error adjustments	_____ **g**

3. **Powder-liquid preparation:**

A. Triturate the Azithromycin (Dihydrate) (amount determined from Step 2Aii) to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 3A) with the Glycerin.

End result: Homogeneous liquid-like dispersion.

4. **Medium integration:**

A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle):

-Cherry Flavor (Artificial)
-Banana Cream Flavor
-Homogeneous liquid-like dispersion (Step 3B)

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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5. **Filling to volume:**

A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 4A) 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. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 5A).

B. Test the pH of the sample. It should lie between 9 and 11.

C. If the pH < 9, carefully add the Sodium Hydroxide 10% Solution in a dropwise manner 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 9 to 11 is obtained.

IMPORTANT: Do not allow the pH to rise above 11.

D. If the pH > 11, carefully add the Hydrochloric Acid 10% Solution in a dropwise manner to the mixture:

1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.
3. Re-test the pH.
4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 9 to 11 is obtained.

IMPORTANT: Do not allow the pH to fall below 9.

7. **Product transfer:**

A. 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		**10 days, refrigerated.**	Packaging Requirements		- Tightly closed dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Cap tightly after use.	
	2	Keep out of reach of children.	6	**Shake well before use.**	
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	7	Keep refrigerated. Do not freeze.	
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	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 active 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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