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Suggested Formula	Azithromycin Dihydrate 209.6 mg/5 mL Preservative Free Oral Liquid (Suspension, 100 mL)	FIN	F 004 026V2

Note: Azithromycin Dihydrate 209.6 mg/5 mL is equivalent to Azithromycin 200 mg/5 mL

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Azithromycin (Dihydrate), USP	4.192	g				
Stevia Powder	0.30	g				
Cherry (flavor)(artificial)	0.3	mL				
Banana Cream (flavor)	0.5	mL				
Glycerin, USP	5.0	mL				
Methylcellulose (1500 CPS), USP	0.75	g				
Purified Water, USP	80.0	mL				
Purified Water, USP	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, Stevia Powder, Methylcellulose (1500 CPS)*

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
Azithromycin (Dihydrate), USP	4.192	g			
Stevia Powder	0.30	g			
Cherry (flavor)(artificial)	0.3	mL			
Banana Cream (flavor)	0.5	mL			
Glycerin, USP	5.0	mL			
Methylcellulose (1500 CPS), USP	0.75	g			
Purified Water, USP	80.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Sodium Hydroxide 10% solution	As required				
Hydrochloric Acid 10% solution	As required				

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

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Azithromycin (Dihydrate) -Stevia Powder B. Levigate the fine, homogeneous powder blend (Step 1A) with the Glycerin. End result: Homogeneous liquid-like dispersion.
2.	**Medium preparation:** A. Slowly and incrementally add the Methylcellulose (1500 CPS) to the Purified Water (80.0 mL *plus* processing error adjustments). Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.

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3. **Medium Integration:**

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

-Cherry (flavor)(artificial)
-Banana Cream (flavor)
-Homogeneous liquid-like dispersion (Step 1B)

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.

4. **pH testing:**

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

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

C. If the pH < 9, carefully add, in a dropwise fashion, 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 9 to 11 is obtained.

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

D. If the pH > 11, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% solution 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.

5. **Filling to volume:**

A. Add additional Purified Water 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").

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	-Tight, light-resistant dispensing container. -To be administered with metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	**Shake well before use.**
	2	Keep out of reach of children.	8	Protect from light.
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	Cap tightly after use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	10	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Preservative free solution.	11	Keep in a dry place.
	6	Keep refrigerated. Do not freeze.		
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

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