



Suggested Formula	Amoxicillin Trihydrate 1004.4 mg/5 mL, Potassium Clavulanate 148.9 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 002 594v2
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Notes: Amoxicillin Trihydrate 1004.4 mg/5 mL is equivalent to Amoxicillin 875 mg/5 mL.  
Potassium Clavulanate 148.9 mg/5 mL is equivalent to Clavulanic Acid 125 mg/5 mL.

### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amoxicillin Trihydrate, USP	20.088	g				
Potassium Clavulanate, USP	2.978	g				
Propylene Glycol, USP	15.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	35.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible): *Propylene Glycol, Potassium Clavulanate*

**Light Sensitive** (protect from light whenever possible): *Propylene Glycol*

#### 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 <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Amoxicillin Trihydrate, USP	20.088	g			
Potassium Clavulanate, USP §	2.978	g			
Propylene Glycol, USP §	15.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	35.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.

\* Takes into account increased batch size conversions and density conversions, if required.

### Preparatory Instruction

1.	<b><u>Powder-liquid preparation:</u></b>  A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:  -Amoxicillin Trihydrate -Potassium Clavulanate  B. Levigate the fine, homogeneous powder blend (Step 1A) with the Propylene Glycol.  <u>End result:</u> Homogeneous paste-like dispersion.
2.	<b><u>Medium integration:</u></b>  A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle).  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous liquid-like dispersion.
3.	<b><u>Filling to volume:</u></b>  A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous liquid-like dispersion.



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4.	<p><b><u>Product transfer:</u></b></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>
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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	10 days, refrigerated.	Packaging Requirements	- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered dose-measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.
	2	Keep out of reach of children.	7	<b>Shake well before use.</b>
	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.	8	Keep refrigerated. Do not freeze.
	4	Protect from light.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	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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