MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Amoxicillin 250 mg / 5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 000 338v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amoxicillin (Trihydrate), USP	TBD					
Xanthan Gum, NF	0.20	g				
Methylparaben, NF	0.15	g				
Glycerin, USP	5.0	mL				
Sorbitol Solution (70%), NF	30.0	mL				
Raspberry Flavor	1.0	mL				
Orange Flavor	1.0	mL				
Purified Water, USP	50.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Sodium Hydroxide 1 N Solution	As needed					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Sorbitol Solution, Glycerin*

Plastic Reactive / Adsorbent *(do not allow to come into contact):* *Methylparaben*

Light Sensitive *(protect from light whenever possible):* *Amoxicillin*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors 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
Amoxicillin (Trihydrate), USP §	TBD				
Xanthan Gum, NF	0.20	g			
Methylparaben, NF §	0.15	g			
Glycerin, USP §	5.0	mL			
Sorbitol Solution (70%), NF §	30.0	mL			
Raspberry Flavor	1.0	mL			
Orange Flavor	1.0	mL			
Purified Water, USP	50.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Sodium Hydroxide 1 N Solution	As needed				

* 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 Amoxicillin (Trihydrate) based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Amoxicillin (Trihydrate), 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 Amoxicillin (Trihydrate) in g/g	_____

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2. **Ingredient quantification:**

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

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

-Amoxicillin (Trihydrate) (amount determined in step 2Aii)
-Xanthan Gum
-Methylparaben

B. Levigate the fine, homogeneous powder blend with the Glycerin.

End result: Homogeneous paste-like dispersion.

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4. **Liquid preparation:**

A. Incrementally add the following ingredients to the Purified Water (50.0 mL *plus* processing error adjustments):

-Sorbitol Solution (70%)
-Raspberry Flavor
-Orange Flavor

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

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. **pH testing:**

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

B. Test the pH of the sample. It should lie between 5.1 and 6.1.

C. If the pH < 5.1, carefully add, in a dropwise fashion, the Sodium Hydroxide 1 N Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 1 N Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 1 N Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 1 N Solution until the pH of 5.1 to 6.1 is obtained.

IMPORTANT: Do not allow the pH to rise above 6.1.

7. **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.

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8.	**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.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	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		May impair mental and/or physical ability. Use care when operating a car or machinery.
	2	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	7		Do not use if irreversible caking or sedimentation occurs.
	3	Keep refrigerated. Do not freeze	8		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	**Shake well before use.**	9		Keep out of reach of children.
	5	Cap tightly after use.	10		Protect from light.
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.			

REFERENCES

1.	Amoxicillin (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 96.
2.	USP <795>. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
3.	Amoxicillin. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 2nd Edition.* American Pharmaceutical Association; 2000: 19.