MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
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technicalservices@medisca.net

Suggested Formula	Amoxicillin 250 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 009 743

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amoxicillin (250 mg) Capsule	30	Units				
Strawberry Flavor	0.3	mL				
Banana Flavor	0.3	mL				
Stevia Powder	0.75	g				
Glycerin, USP	10.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 150.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Stevia Powder, Glycerin*

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

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: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 150 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Amoxicillin (250 mg) Capsule §	30	Units			
Strawberry Flavor	0.3	mL			
Banana Flavor	0.3	mL			
Stevia Powder §	0.75	g			
Glycerin, USP §	10.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 150.0	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.

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Preparatory Instruction

1. **Ingredient quantification (determine the actual quantity of Amoxicillin (250 mg) capsule powder mix to weigh):**

A. Empty and weigh the contents of 33 Amoxicillin (250 mg) Capsules.
Record the total weight here: _____ g

B. Calculate the average weight of powder in each capsule:

Weight of powder from 33 capsules (from Step 1A): _____ g

DIVIDED BY

Number of capsules: 33

EQUALS

Average weight of a single Amoxicillin (250 mg) Capsule: _____ g

C. Calculate the weight of powder equivalent to 30 capsules:

Average weight of a single Amoxicillin (250 mg) Capsule (from Step 1B): _____ g

MULTIPLIED BY

Number of capsules required: 30

EQUALS

Weight of powder equivalent to 30 capsules: _____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 30 capsules (from Step 1C): _____ g

MULTIPLIED BY

Processing error adjustments (5 to 9%): 1.05 to 1.09

EQUALS

Weight of powder required *plus* processing error adjustments: _____ **g**

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2.	**Powder-liquid preparation:** A. Triturate the contents of the 33 Amoxicillin (250 mg) Capsules to form a fine, homogeneous powder. B. Weigh the quantity Amoxicillin (250 mg) capsule powder mix required for the batch (refer to Step 1D) and discard the remaining powder.
3.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Amoxicillin 250 mg capsule powder mix (amount weighed from Step 2B) -Stevia Powder B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Glycerin -Strawberry Flavor -Banana Flavor C. Levigate the fine, homogeneous powder blend (Step 3A) with the homogeneous liquid-like solution (Step 3B). End result: Homogeneous paste-like dispersion.
4.	**Medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 3C) to the Oral Mix (Flavored Suspending Vehicle) (50.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
5.	**Filling to volume:** A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 4A) to fill to the required batch size (150.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.

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6. **pH testing:**

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

B. Test the pH of the sample. It should lie between 6.0 and 6.5.

C. If the pH < 6.0 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.
2. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 6.0 to 6.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 6.5.

D. If the pH > 6.5, carefully add in a dropwise manner 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 6.0 to 6.5 is obtained.

IMPORTANT: Do not allow the pH to fall below 6.0.

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		**14 days**, refrigerated, as per USP 795*.	Packaging Requirements		- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Keep out of reach of children.
	2	Keep refrigerated (2°C – 8°C). Do not freeze.		7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	**Shake well before use.**		8	Cap tightly after use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.		9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	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.			

*** If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.**

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REFERENCES

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2. Amoxicillin. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 216.
3. Amoxicillin (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2012: Monograph #574.
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