MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Azithromycin 200 mg Oral Gummy Gels (Solid Suspension, 6 x 0.9 mL Gummy Gels)	FIN	F 008 183

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Azithromycin (Dihydrate), USP	TBD					
Stevia Powder	0.03	g				
Cherry Flavor	0.05	mL				
Vanilla Flavor	0.03	mL				
Colloidal Silicon Dioxide, NF	0.06	g				
Glycerin, USP	1.0	mL				
Medisca Gum Base (Gelatin)	TBD					

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Stevia Powder, Colloidal Silicon Dioxide, Glycerin, Gum Base*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and considerations during preparation, it is suggested to measure an additional **25 to 30%** 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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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 6 x 0.9 mL Gummy Gels)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Azithromycin (Dihydrate), USP	TBD				
Stevia Powder §	0.03	g			
Cherry Flavor	0.05	mL			
Vanilla Flavor	0.03	mL			
Colloidal Silicon Dioxide, NF §	0.06	g			
Glycerin, USP §	1.0	mL			
Medisca Gum Base (Gelatin) §	TBD				

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

Preparatory Instruction	
1.	**Preparatory step:** A. Prepare a hot water bath. Specifications: Temperature: 60 to 65°C.

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2. **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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3. **Ingredient quantification:**

A. Determine the quantity (in g) of Azithromycin (Dihydrate) required to make 6 Gummy Gels of Azithromycin 200 mg:

Quantity of Azithromycin (Dihydrate) required for each Gymmy Gel	0.200 g
DIVIDED BY	
Potency of Azithromycin (Dihydrate) in g/g (Step 2Ai)	_____
EQUALS	
i. Quantity of Azithromycin (Dihydrate) needed for each Gummy Gel	_____ **g**
MULTIPLIED BY	
Number of Gummies	6
EQUALS	
ii. Quantity of Azithromycin (Dihydrate) needed for 6 Gummies	_____ **g**
MULTIPLIED BY	
Processing error adjustments (25 to 30%)	1.25 to 1.30
EQUALS	
iii. Total quantity of Azithromycin (Dihydrate) needed *plus* processing error adjustments	_____ **g**

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4. **Ingredient quantification:**

A. Determine the actual quantity of Gum Base (Gelatin) to weigh for the required batch size (6 Gummies):

Total Volume of the batch (6 x 0.9 mL)	5.4 mL
MINUS	
Total amount of liquid ingredients and liquid equivalent of ingredients with known true density (Colloidal Silicon Dioxide)	1.11 mL
EQUALS	
Quantity of Gum Base (Gelatin) in mL	_____ mL
MULTIPLIED BY	
Gum Base (Gelatin) density	1.334 g/mL
EQUALS	
Weight of Gum Base (Gelatin) in g	_____ g
MINUS	
The weight of (Azithromycin (Dihydrate) (Step 3Aii) + Stevia Powder X 0.7 (Displacement factor)	_____ g
EQUALS	
i. Quantity of Gum Base (Gelatin) needed for 6 Gummies	_____ g
MULTIPLIED BY	
Processing error adjustments (25 to 30%)	1.25 to 1.30
EQUALS	
ii. Weight of Gum Base (Gelatin) required *plus* processing error adjustments	_____ g

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5. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Azithromycin (Dihydrate) (amount determined from Step 3Aiii)
-Stevia Powder
-Colloidal Silicon Dioxide

B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution.

-Glycerin
-Cherry Flavor
-Vanilla Flavor

C. Levigate the fine, homogeneous powder blend (Step 5A) with the homogeneous liquid-like solution (Step 5B).

End result: Homogeneous paste-like dispersion.

6. **Medium integration:**

A. Using the hot water bath, heat the Gum Base (Gelatin) until molten.

Specifications: Maintain temperature between 60°C and 65°C.

IMPORTANT: Do not allow the temperature to exceed 65°C.

B. Using the hot water bath, incrementally add the homogeneous paste-like dispersion (Step 5C) to the molten Gum Base (Gelatin) (Step 6A).

Specifications: Continuously mix, using high-shear mixing techniques.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous liquid-like dispersion.

IMPORTANT: Do not allow the temperature to exceed 65°C.

C. Remove the mixture from the heat and allow it to cool down to 55°C.

7. **Mold filling:**

A. Fill each of the 6 mold cavities with the mixture (Step 6C). If the mixture starts to solidify while filling, reheat to 55 to 60°C, and continue.

B. Allow to cool until the mixture has completely solidified.

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8.	**Validation technique:** A. Weigh 6 Gummy Gels separately. B. The final weight of each Gummy Gel from Step 8A (not including the weight of the empty gummy gel mold) shall not be less than 90% and not more than 110% of the theoretically calculated in accordance to USP guidelines. The theoretically calculated weight should be the total of the following values: **Step 3Ai + Step 4Ai/6 + 0.239 g**.
9.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, refrigerated, as per USP.	Packaging Requirements	Individually wrapped in a tight foil and placed in a box or wide-mouth container.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	6	May impair mental and/or physical ability. Use care when operating a car or machinery.
	3	Keep out of reach of children.	7	Cap tightly after use.
	4	Keep refrigerated. Do not freeze.	8	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
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.			

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