MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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| Suggested Formula | Azithromycin 200 mg/5 mL Oral Liquid (Suspension, 100 mL) | FIN | F 004 074v2 |
|---|---|---|---|

## SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---|---|---|---|---|---|
| Azithromycin (250 mg) Tablets** | 16 | Units | | | | |
| Glycerin, USP | 20.0 | mL | | | | |
| Cherry Flavor (Artificial) | 0.3 | mL | | | | |
| Banana Cream Flavor | 0.5 | mL | | | | |
| Medisca Oral Suspend (Suspending Vehicle) | 35.0 | mL | | | | |
| Medisca Oral Syrup (Flavored Vehicle) | q.s. to 100.0 | mL | | | | |
| Sodium Hydroxide 10% Solution | As required | | | | | |
| Hydrochloric Acid 10% Solution | As required | | | | | |

**Delivered as Azithromycin Dihydrate.

## SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

***Hygroscopic*** *(protect from moisture whenever possible):* *Glycerin*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error 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 |
|---|---|---|---|---|---|
| Azithromycin (250 mg) Tablets | 16 | Units | | | |
| Glycerin, USP § | 20.0 | mL | | | |
| Cherry Flavor (Artificial) | 0.3 | mL | | | |
| Banana Cream Flavor | 0.5 | mL | | | |
| Medisca Oral Suspend (Suspending Vehicle) | 35.0 | mL | | | |
| Medisca Oral Syrup (Flavored Vehicle) | 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.

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## Preparatory Instruction

1. **Ingredient quantification (determine the actual quantity of Azithromycin (250 mg) tablet powder to weigh):**

A. Weigh 18 Azithromycin (250 mg) Tablets. Record the total weight here: _____ g

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

| | |
|---|---|
| Weight of 18 tablets (from Step 1A): | _____ g |
| DIVIDED BY | |
| Number of tablets: | 18 |
| EQUALS | |
| Average weight of a single Azithromycin (250 mg) Tablet: | _____ g |

C. Calculate the weight of powder equivalent to 16 tablets:

| | |
|---|---|
| Average weight of a single Azithromycin (250 mg) Tablet (from Step 1B): | _____ g |
| MULTIPLED BY | |
| Number of tablets required: | 16 |
| EQUALS | |
| Weight of powder equivalent to 16 tablets: | _____ g |

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

| | |
|---|---|
| Weight of powder equivalent to 16 tablets (from Step 1C): | _____ g |
| MULTIPLED 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 preparation:**<br><br>A. Crush and triturate the 18 Azithromycin (250 mg) Tablets into a **fine** homogeneous powder.<br><br>B. Weigh the quantity of Azithromycin (250 mg) tablet powder mix required for the batch (refer to Step 1D) and discard the remaining powder. |
| 3. | **Powder-liquid preparation:**<br><br>A. Levigate the Azithromycin (250 mg) tablet powder mix (amount weighed in Step 2B) with the Glycerin.<br><br>End result: Homogeneous paste-like dispersion. |
| 4. | **Medium Integration:**<br><br>A. In the given order, sequentially add the following ingredients to the Oral Suspend (Suspending Vehicle):<br><br>-Cherry Flavor (Artificial)<br>-Banana Cream Flavor<br>-Homogeneous paste-like dispersion (Step 3A)<br><br>Specifications: Continuously mix, using high-shear mixing techniques.<br><br>End result: Homogeneous liquid-like dispersion.<br><br>Note: Add the next ingredient, once the previous one has been completely added and dispersed. |
| 5. | **Filling to volume:**<br><br>A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 4A) to fill to the required batch size (100.0 mL *plus* processing error adjustments).<br><br>Specifications: Continuously mix, using high-shear mixing techniques.<br><br>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 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.

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 | | 10 days, refrigerated. | Packaging Requirements | | - Tightly closed, light-resistant dispensing bottle.<br>- To be administered with a metered dose-measuring device. |
| Auxiliary Labels | 1 | Use as directed. Do not exceed prescribed dose. | 6 | **Shake well before use.** | |
| | 2 | Keep out of reach of children. | 7 | 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. | 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 | 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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