MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Ranitidine 150 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 163

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ranitidine Hydrochloride, USP*	3.348	g				
Stevia Powder	0.30	g				
Bitterness Reducing Agent (NF01) (Natural) (Powder)	0.50	g				
Propylene Glycol, USP	3.0	mL				
Cherry Flavor	1.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					

*Note: Ranitidine Hydrochloride 3.348 g is equivalent to Ranitidine 3.000 g.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Ranitidine Hydrochloride, Stevia Powder, Propylene Glycol*

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

Moisture sensitive *(protect from humidity whenever possible):* *Ranitidine Hydrochloride*

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
Ranitidine Hydrochloride, USP §	3.348	g			
Stevia Powder §	0.30	g			
Bitterness Reducing Agent (NF01) (Natural) (Powder)	0.50	g			
Propylene Glycol, USP §	3.0	mL			
Cherry Flavor	1.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				

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

Preparatory Instruction	
1.	**Powder-liquid preparation:** A. Triturate the following ingredients together to form a fine, homogeneous powder blend. -Ranitidine Hydrochloride -Stevia Powder -Bitterness Reducing Agent (NF01) (Natural) (Powder) B. Levigate the fine, homogeneous powder blend (Step 1A) with the Propylene Glycol. End result: Homogeneous liquid-like dispersion.

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2. **Medium integration:**

A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (50.0 mL *plus* processing error adjustments):

-Cherry Flavor
-Homogeneous liquid-like dispersion (Step 1B)

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.

3. **Filling to volume:**

A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 2A) 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.

4. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 3A).

B. Test the pH of the sample. It should lie between 6.7 and 7.5.

C. If the pH < 6.7, 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.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 6.7 to 7.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 7.5.

5. **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.	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		**Shake well before use.**
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	8		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Protect from light.	9		Keep refrigerated. Do not freeze.
	5	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 active to the dispensing container as deemed necessary.			
Patient Instructions		Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

1.	Suspensions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 239.
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