



Suggested Formula	Hydrochlorothiazide 13 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 003 362v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydrochlorothiazide, USP	1.300	g				
Glycerin, USP	5.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL				
Medisca Oral Syrup SF (Flavored Syrup Vehicle Sugar-Free)	q.s. to 100.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

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

#### 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: 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 <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Hydrochlorothiazide, USP §	1.300	g			
Glycerin, USP §	5.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL			
Medisca Oral Syrup SF (Flavored Syrup Vehicle Sugar-Free)	q.s. to 100.0	mL			

\* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><b><u>Powder-Liquid preparation:</u></b></p> <p>A. Triturate the Hydrochlorothiazide to form a fine homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 1A) with the Glycerin.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
2.	<p><b><u>Medium Integration:</u></b></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle) (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add Oral Syrup SF (Flavored Syrup Vehicle Sugar-Free) to the mixture (Step 2A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous suspension.</p>



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4.	<p><b><u>Product transfer:</u></b></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>
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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.	5	Protect from light.
	2	Keep out of reach of children.	6	Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	7	<b>Shake well before use.</b>
	4	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			



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## REFERENCES

1.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2003: 257.
2.	Hydrochlorothiazide (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #4781.
3.	Hydrochlorothiazide (Monograph). <i>United States Pharmacopeia XXXI / National Formulary 26</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
4.	Hydrochlorothiazide. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26<sup>th</sup> Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1227.
5.	USP <795>. <i>United States Pharmacopeia XXXI / National Formulary 26</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2008.

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