



MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

9/23/2020; Page 1

| | | | |
|-------------------|---|-----|-------------|
| Suggested Formula | Hydrochlorothiazide 13 mg/mL Oral Liquid (Suspension, 100 mL) | FIN | F 003 362v3 |
|-------------------|---|-----|-------------|

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 (Sugar-Free Flavored Syrup Vehicle) | q.s. to 100.0 | mL | | | | |





| | | | |
|-------------------|---|-----|-------------|
| Suggested Formula | Hydrochlorothiazide 13 mg/mL Oral Liquid (Suspension, 100 mL) | FIN | F 003 362v3 |
|-------------------|---|-----|-------------|

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: 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 (GFI) 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.



| | | | |
|-------------------|---|-----|-------------|
| Suggested Formula | Hydrochlorothiazide 13 mg/mL Oral Liquid (Suspension, 100 mL) | FIN | F 003 362v3 |
|-------------------|---|-----|-------------|

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 |
|---|---------------|------|----------------------------------|------------------|-----------------|
| Hydrochlorothiazide, USP § | 1.300 | g | | | |
| Glycerin, USP § | 5.0 | mL | | | |
| Medisca Oral Suspend (Suspending Vehicle) | 50.0 | mL | | | |
| Medisca Oral Syrup SF (Sugar-Free Flavored Syrup Vehicle) | 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><u>Powder-Liquid preparation:</u></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><u>Medium Integration:</u></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><u>Filling to volume:</u></p> <p>A. Add Oral Syrup SF (Sugar-Free Flavored Syrup Vehicle) 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> |



| | | | |
|-------------------|---|-----|-------------|
| Suggested Formula | Hydrochlorothiazide 13 mg/mL Oral Liquid (Suspension, 100 mL) | FIN | F 003 362v3 |
|-------------------|---|-----|-------------|

| | |
|----|---|
| 4. | <p><u>Product transfer:</u></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> |
|----|---|

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-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 (2°C – 8°C). Do not freeze. | 7 | Shake well before use. |
| | 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. | | | |



| | | | |
|-------------------|---|-----|-------------|
| Suggested Formula | Hydrochlorothiazide 13 mg/mL Oral Liquid (Suspension, 100 mL) | FIN | F 003 362v3 |
|-------------------|---|-----|-------------|

REFERENCES

| | |
|----|--|
| 1. | Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 257. |
| 2. | Hydrochlorothiazide (Monograph). In: O'Neil MJ. <i>The Merck Index 14th 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, 26th 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. |

DISCLAIMER: THIS DOCUMENT IS COPYRIGHT© 2019-2020 MEDISCA PHARMACEUTIQUE INC. MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY, SCHEDULING OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW. MEDISCA NETWORK INC. MAKES NO WARRANTIES WITH RESPECT TO INFRINGEMENT OR NON-INFRINGEMENT BY THE FORMULA OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY OF ANY OTHER PARTY, AND IT IS THE RESPONSIBILITY OF THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO INVESTIGATE AND DETERMINE ANY SUCH ISSUE.