



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	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v3
-------------------	---	-----	-------------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Losartan Potassium, USP	0.100	g				
Glycerin, USP	5.0	mL				
Tutti Frutti Flavor	0.5	mL				
Medisca Oral Suspend (Suspending Vehicle)	40.0	mL				
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 80.0	mL				





Suggested Formula	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v3
-------------------	---	-----	-------------

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 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 (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.



Suggested Formula	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v3
-------------------	---	-----	-------------

SUGGESTED PREPARATION (for 80 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : ____	Processing Error	Qty. to measure
Losartan Potassium, USP	0.100	g			
Glycerin, USP §	5.0	mL			
Tutti Frutti Flavor	0.5	mL			
Medisca Oral Suspend (Suspending Vehicle)	40.0	mL			
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 80.0	mL			

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1.	<p><u>Powder-liquid preparation:</u></p> <p>A. Triturate the Losartan Potassium 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>Liquid preparation:</u></p> <p>A. Combine and mix the following ingredients together:</p> <p>-Tutti Frutti Flavor -Oral Suspend (Suspending Vehicle)</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><u>Medium integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the homogeneous liquid-like dispersion (Step 2A).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>



Suggested Formula	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v3
-------------------	---	-----	-------------

4.	<p><u>Filling to volume:</u></p> <p>A. Add Oral Syrup (Flavored Syrup Vehicle) to the mixture (Step 3A) to fill to the required batch size (80.0 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>
5.	<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 dispensing bottle. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	Shake well before use.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	7	Keep refrigerated (2°C – 8°C). Do not freeze.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	8	May impair mental and/or physical ability. Use care when operating a car or machinery.
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.			



Suggested Formula	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v3
-------------------	---	-----	-------------

REFERENCES

1.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 257.
2.	Losartan (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 1000.
3.	Losartan Potassium (Monograph). <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 1155.
4.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
5.	Losartan Potassium. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1965.

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.