

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

5/2/2013; Page 1

Suggested	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v2
Formula	Losartan i otassiani 0.25 mg/5 mL Orar Elquid (Suspension, 60 mL)	1 11 1	1 002 332 42

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 Vehicle)	q.s. to 80.0	mL	Ċ			

SPECIAL PREPARATORY CONSIDERATIONS

]	Ingredient-Sp	pecific	Inform	ation

Hygroscopic (protect from moisture whenever possible):

Light Sensitive (protect from light whenever possible):

G	lycerin	

Losartan Potassium

Suggested Preparatory Guidelines

Non-Sterile Preparat	tion Sterile Preparation
<u>Processing Error /</u> <u>Testing Considerations</u> :	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.



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

5/2/2013; Page 2

Suggested Formula	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v2
----------------------	---	-----	-------------

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 Vehicle)	q.s. to 80.0	mL	Y.C.		

§ 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 Losartan Potassium to form a fine, homogeneous powder.							
	B. Levigate the fine, homogeneous powder (Step 1A) with the Glycerin.							
	End result: Homogeneous liquid-like dispersion.							
2.	Liquid preparation:							
	A. Combine and mix the following ingredients together:							
	-Tutti Frutti Flavor -Oral Suspend (Suspending Vehicle)							
	End result: Homogeneous liquid-like dispersion.							
3.	Medium integration:							
	A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the homogeneous liquid-like dispersion (Step 2A).							
	Specifications: Continuously mix.							
	End result: Homogeneous liquid-like dispersion.							



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

5/2/2013; Page 3

Suggested Formula		Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v2						
4.		g to volume:	vize (8() 0 mL <i>plus</i>						
	A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 3A) to fill to the required batch size (80.0 mL <i>plus</i> processing error adjustments).									
	<u>Specifications</u> : Continuously mix. <u>End result</u> : Homogeneous liquid-like dispersion.									
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.									
GGESTED PRESENTATION										

SUGGESTED PRESENTATION

	Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaş equirem		 Tightly closed, light-resistant dispensing bottle. To be administered with a metered dose- measuring device.
		1	Use as directed. Do not exceed presc dose.	cribed	6	Cap tightly after use.
		2	Keep out of reach of children.		7	Shake well before use.
	Auxiliary Labels	3	Consult your health care practitioner is other prescription or over-the-co- medications are currently being used of prescribed for future use.	ounter	8	Keep refrigerated. Do not freeze.
		4	Do not take with alcohol, sleep tranquilizers or other CNS depressants.		9	May impair mental and/or physical ability. Use care when operating a car or machinery.
			Protect from light.			
	Pharmacist Instructions	Ad	d any auxiliary labels specific to the acti	ive to th	e disp	pensing container as deemed necessary.
	Patient Instructions	Co	18.			



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

5/2/2013; Page 4

Suggested Formula	Losartan Potassium 6.25 mg/5 mL Oral Liquid (Suspension, 80 mL)	FIN	F 002 332v2	
----------------------	---	-----	-------------	--

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>. United States Pharmacopeia XXVIII / National Formulary 23. Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
5.	Losartan Potassium. Thomson Micromedex. USP DI – Drug Information for the Health Care Professional, 26 th Edition. Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1965.

DISCLAIMER: 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 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. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST 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 OF INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.