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

Suggested Formula	Lopinavir 200 mg/5 mL, Ritonavir 50 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 001 695v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lopinavir/Ritonavir (200/50 mg) Tablets	30	Units				
Glycerin, USP	15.0	mL				
Tutti Frutti Flavor	1.5	mL				
Medisca Oral Suspend (Suspending Vehicle)	70.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 150.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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

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 **3 to 5%** 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
technicalservices@medisca.net

Suggested Formula	Lopinavir 200 mg/5 mL, Ritonavir 50 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 001 695v2

SUGGESTED PREPARATION (for 150 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Lopinavir/Ritonavir (200/50 mg) Tablets §	30	Units			
Glycerin, USP §	15.0	mL			
Tutti Frutti Flavor	1.5	mL			
Medisca Oral Suspend (Suspending Vehicle)	70.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 150.0	mL			

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

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

Suggested Formula	Lopinavir 200 mg/5 mL, Ritonavir 50 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 001 695v2

Preparatory Instruction

1. **Ingredient quantification (determine the actual quantity of Lopinavir/Ritonavir (200/50 mg) tablet powder to weigh if accounting for processing error adjustments):**

A. Weigh 32 Lopinavir/Ritonavir (200/50 mg) Tablets. Record the total weight here: _____ g

B. Calculate the average weight of powder in each tablet:

Weight of 32 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets	32
EQUALS	
Average weight of a single Lopinavir/Ritonavir (200/50 mg) Tablet:	_____ g

C. Calculate the weight of powder equivalent to 30 tablets:

Average weight of a single Lopinavir/Ritonavir (200/50 mg) Tablet (from Step 1B):	_____ g
MULTIPLED BY	
Number of tablets required:	30
EQUALS	
Weight of powder equivalent to 30 tablets:	_____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 30 tablets (from Step 1C):	_____ g
MULTIPLED BY	
Processing error adjustments (3 to 5%):	1.03 to 1.05
EQUALS	
Weight of powder required *plus* processing error adjustments:	_____ **g**

Suggested Formula	Lopinavir 200 mg/5 mL, Ritonavir 50 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 001 695v2

2.	**Powder preparation:** A. Crush and triturate the 32 Lopinavir/Ritonavir (200/50 mg) Tablets to form a fine, homogeneous powder. B. Weigh the quantity of Lopinavir/Ritonavir (200/50 mg) tablet powder required for the batch (refer to Step 1D) and discard the remaining powder. C. Levigate the fine, homogeneous powder (amount weighed in Step 2B) with the Glycerin. End result: Homogeneous liquid-like dispersion.
3.	**Liquid preparation:** A. Combine and mix the following ingredients together to form a homogeneous liquid-like dispersion: -Tutti Frutti Flavor -Oral Suspend (Suspending Vehicle)
4.	**Medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 2C) to the homogeneous liquid-like dispersion (Step 3A). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
5.	**Filling to volume:** A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 4A) to fill to the required batch size (150.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
6.	**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.

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

Suggested Formula	Lopinavir 200 mg/5 mL, Ritonavir 50 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 001 695v2

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		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.	7		Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	8		**Shake well before use.**
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9		Protect from light.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.			
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions		Contact your pharmacist in the event of adverse reactions.			

Suggested Formula	Lopinavir 200 mg/5 mL, Ritonavir 50 mg/5 mL Oral Liquid (Suspension, 150 mL)	FIN	F 001 695v2

REFERENCES

1.	Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 257.
2.	Ritonavir. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 34th Edition*. London, England: The Pharmaceutical Press; 2005: 653.
3.	Ritonavir (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 1479.
4.	Lopinavir. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 34th Edition.* London, England: The Pharmaceutical Press; 2005: 649
5.	Lopinavir (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 998.
6.	UPS <795>. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.