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	Isosorbide Mononitrate 60 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 915v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Isosorbide Mononitrate	1.200	g				
Glycerin, USP	3.0	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

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.

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	Isosorbide Mononitrate 60 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 915v2

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
Isosorbide Mononitrate	1.200	g			
Glycerin, USP §	3.0	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.	**Powder-liquid preparation:** A. Triturate the Isosorbide Mononitrate to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with the Glycerin. End result: Homogeneous liquid-like dispersion.
2.	**Powder-liquid preparation to medium incorporation:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** 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 *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.

Suggested Formula	Isosorbide Mononitrate 60 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 915v2

4.	**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.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	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	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	6	May impair mental and/or physical ability. Use care when operating a car or machinery.
	3	Keep refrigerated. Do not freeze.	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Keep out of reach of children.	8	**Shake well before use.**
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	Isosorbide Mononitrate 60 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 915v2

REFERENCES

1. Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 257.
2. Isosorbide Dinitrate (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 935.
3. USP <795>. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
4. Isosorbide Mononitrate. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2205.