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	Cefixime 100 mg /5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 077

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Cefixime (Trihydrate), USP	TBD					
Stevia Powder	0.30	g				
Strawberry Flavor	1.0	mL				
Glycerin, USP	2.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	45.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Cefixime, Glycerin, Stevia Powder*

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

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	Cefixime 100 mg /5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 077

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
Cefixime (Trihydrate), USP §	TBD				
Stevia Powder §	0.30	g			
Strawberry Flavor	1.0	mL			
Glycerin, USP §	2.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	45.0	mL			
Medisca Oral Syrup (Flavored 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. **Ingredient quantification:**

A. Determine the potency of Cefixime (Trihydrate) based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Cefixime (Trihydrate), in decimal	_____
MULTIPLY BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ µg/mg
MULTIPLY BY (Multiplication factor – µg to grams /mg to grams)	0.001
EQUALS	
i. Potency of Cefixime (anhydrous basis) in g/g	_____

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	Cefixime 100 mg /5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 077

2. **Ingredient quantification:**

A. Determine the quantity (in g) of Cefixime (Trihydrate) required to make a 100 mL batch of Cefixime (anhydrous basis) 100 mg/5 mL Oral Liquid:

Quantity of Cefixime (anhydrous basis) required for 100 mL	2.000 g
DIVIDED BY	
Potency of Cefixime (anhydrous basis) in g/g (Step 1Ai)	_____
EQUALS	
i. Quantity of Cefixime (Trihydrate) needed for 100 mL	_____ **g**
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Cefixime (Trihydrate) needed *plus* processing error adjustments	_____ **g**

3. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Cefixime (Trihydrate) (amount determined in Step 2Aii)
-Stevia Powder

B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution:

-Glycerin
-Strawberry Flavor

C. Levigate the fine, homogeneous powder blend (Step 3A) with the homogeneous liquid-like solution (Step 3B).

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

Suggested Formula	Cefixime 100 mg /5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 077

4.	**Medium incorporation:** A. Incrementally add the homogenous liquid-like dispersion (Step 3C) to the Oral Suspend (Suspending Vehicle). Specifications: Continuously mix, using high-shear mixing techniques. 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 (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
6.	**Product transfer:** A. Transfer the final product into the specified dispensing container (see "Packaging requirements").

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.	5	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Protect from light.	6	Keep out of reach of children.
	3	Keep refrigerated. Do not freeze.	7	Cap tightly after use.
	4	**Shake well before use.**		
Pharmacist Instructions		Add any auxiliary labels specific to the active ingredients to the dispensing container as deemed necessary.		
Patient Instructions		Contact your pharmacist in the event of adverse reactions.		

Suggested Formula	Cefixime 100 mg /5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 077

REFERENCES

1. Suspensions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 209.
2. Suprax. In: *Physicians Desk Reference ®.* Montvale, NJ: Thomson PDR; 2009: 1891.
3. Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 283.
4. Cefixime. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 224.
5. Cefixime (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #1924.
6. Cefixime (Monograph). *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 2203.
7. Cefixime. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 833.
8. USP <795>. *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.