



Suggested Formula	Ibuprofen 100 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 170
-------------------	--	-----	-----------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ibuprofen, USP	2.000	g				
Glycerin, USP	5.0	mL				
Tutti Frutti Flavor	1.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	45.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible):

Glycerin

Light Sensitive (protect from light whenever possible):

Ibuprofen

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.



Suggested Formula	Ibuprofen 100 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 170
-------------------	--	-----	-----------

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
Ibuprofen, USP §	2.000	g			
Glycerin, USP §	5.0	mL			
Tutti Frutti Flavor	1.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	45.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	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 Ibuprofen 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>Medium integration:</u></p> <p>A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (45.0 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none">-Tutti Frutti Flavor-Homogeneous liquid-like dispersion (Step 1B) <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p>



Suggested Formula	Ibuprofen 100 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 170
-------------------	--	-----	-----------

3.	<p>Filling to volume:</p> <p>A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 2A) to fill to the required batch size (100.0 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>
4.	<p>Product transfer:</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		Packaging Requirements	
14 days, refrigerated, as per USP.			- Tightly closed, light-resistant dispensing bottle. - To be dispensed with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 Cap tightly after use.
	2	Keep out of reach of children.	7 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.	8 Keep refrigerated. Do not freeze.
	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.	10 Patient must avoid exposure to sunlight and UV rays.
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	Ibuprofen 100 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 170
-------------------	--	-----	-----------

REFERENCES

1.	Suspensions. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 239.
2.	Motrin (Children's). In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2014</i> : 1775.
3.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 324.
4.	Ibuprofen. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 64.
5.	Ibuprofen (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4919.
6.	Ibuprofen. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 249.
7.	Ibuprofen (Monograph). <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 3300.
8.	Ibuprofen. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 420.
9.	USP <795>. <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.

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 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 TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.