



Suggested Formula	Acetaminophen 100 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 004 369v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acetaminophen, USP	10.000	g				
Propylene Glycol, USP	5.0	mL				
Tutti Frutti Flavor	0.3	mL				
Medisca Oral Suspend (Suspending Vehicle)	45.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible): *Propylene Glycol*

**Moisture Sensitive** (protect from humidity whenever possible): *Acetaminophen*

**Light Sensitive** (protect from light whenever possible): *Acetaminophen, Propylene Glycol*

#### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing 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.



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### 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
Acetaminophen, USP §	10.000	g			
Propylene Glycol, USP §	5.0	mL			
Tutti Frutti Flavor	0.3	mL			
Medisca Oral Suspend (Suspending Vehicle)	45.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				
Hydrochloric Acid 10% Solution	As required				

§ Weigh / measure just prior to use.

\* Takes into account increased batch size conversions and density conversions, if required.

### Preparatory Instruction

1.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. Triturate the Acetaminophen to form a fine, homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 1A) with the Propylene Glycol.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>
2.	<p><b><u>Medium integration:</u></b></p> <p>A. In the given order, sequentially add the following ingredients to the Oral Suspend (Suspending Vehicle):</p> <ul style="list-style-type: none"><li>-Tutti Frutti Flavor</li><li>-Homogeneous paste-like dispersion (Step 1B)</li></ul> <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>



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3.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add Oral Syrup (Flavored 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><b><u>pH testing:</u></b></p> <p>A. Draw an appropriate amount of the mixture (Step 3A).</p> <p>B. Test the pH of the sample. It should lie between 4.0 and 6.9.</p> <p>C. <u>If the pH &lt; 4.0 carefully add in a dropwise manner the Sodium Hydroxide 10% Solution to the mixture:</u></p> <ol style="list-style-type: none"><li>1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.</li><li>2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.</li><li>3. Re-test the pH.</li><li>4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 4.0 to 6.9 is obtained.</li></ol> <p>IMPORTANT: Do not allow the pH to rise above 6.9.</p> <p>D. <u>If the pH &gt; 6.9, carefully add in a dropwise manner the Hydrochloric Acid 10% Solution to the mixture:</u></p> <ol style="list-style-type: none"><li>1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.</li><li>2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.</li><li>3. Re-test the pH.</li><li>4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 4.0 to 6.9 is obtained.</li></ol> <p>IMPORTANT: Do not allow the pH to fall below 4.0</p>
5.	<p><b><u>Product transfer:</u></b></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>



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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date		Packaging Requirements	
	14 days, refrigerated, as per USP.		- 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
	2	Keep out of reach of children.	6
	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.	7
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	8
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.		



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## REFERENCES

1.	Suspensions. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 209.
2.	Tempra. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2010</i> . 2348.
3.	Propylene Glycol. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 6<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2009: 592.
4.	Paracetamol. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 108.
5.	Acetaminophen (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #47.
6.	Acetaminophen. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 4<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2009: 1.
7.	Acetaminophen (Monograph). <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 1388.
8.	Acetaminophen. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26<sup>th</sup> Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 15.
9.	USP <795>. <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.

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