



Suggested Formula	Acetaminophen 225 mg Oral Troches (Solid Suspension, 30 x 0.9 mL Troches)	FIN	F 006 584v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acetaminophen, USP	6.750	g				
Propylene Glycol, USP	3.0	mL				
Cherry Flavor	0.2	mL				
Stevia Powder	0.15	g				
Medisca Troche Base	21.35	g				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

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

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

**Heat Sensitive** (protect from heat whenever possible): *Acetaminophen*

#### 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 **12 to 15%** 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 30 x 0.9 mL Troches)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Acetaminophen, USP §	6.750	g			
Propylene Glycol, USP §	3.0	mL			
Cherry Flavor	0.2	mL			
Stevia Powder §	0.15	g			
Medisca Troche Base	21.35	g			

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

§ Weigh / measure just prior to use.

**Preparatory Instruction**

1.	<p><b><u>Preparatory step:</u></b></p> <p>A. Prepare a hot water bath.</p> <p style="padding-left: 40px;"><u>Specifications:</u> Temperature: 60 to 65°C.</p>
2.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Acetaminophen</li> <li>-Stevia Powder</li> </ul> <p>B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution:</p> <ul style="list-style-type: none"> <li>-Propylene Glycol</li> <li>-Cherry Flavor</li> </ul> <p>C. Levigate the fine, homogeneous powder blend (Step 2A) with the homogeneous liquid-like solution (Step 2B).</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>



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3.	<p><b><u>Powder-liquid to medium integration:</u></b></p> <p>A. Using the hot water bath, melt the Troche Base.</p> <p><b><u>Specifications:</u></b> Continuously mix. Maintain temperature between 60°C and 65°C.</p> <p><b><u>End result:</u></b> Homogeneous liquid-like solution.</p> <p>B. Using the hot water bath, incrementally add the homogeneous paste-like dispersion (Step 2C) to the homogeneous liquid-like solution (Step 3A).</p> <p><b><u>Specifications:</u></b> Continuously mix, using high-shear mixing techniques. Maintain temperature between 60°C and 65°C.</p> <p><b><u>End result:</u></b> Homogeneous liquid-like dispersion.</p> <p><b><u>Important:</u></b> Do not allow the temperature to exceed 65°C.</p>
4.	<p><b><u>Mold filling:</u></b></p> <p>A. Fill the 30 mold cavities with the homogeneous liquid-like dispersion (Step 3B). If the mixture starts to solidify while filling, reheat to 60 to 65°C, and continue.</p> <p>B. Allow to cool until the API mixture has completely solidified.</p> <p><b><u>Note:</u></b> Continuously mix the final product during the mold filling in order to maintain homogeneity.</p>
5.	<p><b><u>Validation technique:</u></b></p> <p>A. Weigh 6 troches separately.</p> <p>B. The final weight of each troche from Step 5A (not including the weight of the troche mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 1.05 g in accordance to USP guidelines.</p>
6.	<p><b><u>Product transfer:</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>



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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	6 months, as per USP*.		Packaging Requirements	Individually wrapped in a tight, light-resistant foil and placed in a box or wide-mouth jar, or dispensed in a troche mold and covered with light-resistant sleeve.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Keep out of reach of children.	6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Cap tightly after use.	7	Protect from light.
	4	Keep at room temperature (20°C – 23°C).	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	If allergic reactions occur, consult your pharmacist.			

\* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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## REFERENCES

1.	Lozenges/Troches. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 183.
2.	Tempra. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2015</i> : 2948.
3.	Propylene Glycol. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 672.
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 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #47.
6.	Acetaminophen. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 2.
7.	Acetaminophen (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 2948.
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 XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.

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