



Suggested Formula	Acetaminophen 300 mg Rectal Suppositories (Solid Suspension, 30 x 1.4 g [1.362 mL] Suppositories)	FIN	F 004 387v4
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Acetaminophen, USP	9.000	g				
Silica Gel (Micronized)	0.75	g				
Medisca SPG Supposi-Base™	30.94	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible): Acetaminophen

Moisture Sensitive (protect from humidity whenever possible): Acetaminophen

Hygroscopic (protect from moisture whenever possible): Silica Gel

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 1.4 g [1.362 mL])

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Acetaminophen, USP §	9.000	g			
Silica Gel (Micronized) §	0.75	g			
Medisca SPG Supposi-Base™	30.94	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><u>Preparatory step:</u></p> <p>A. Prepare a hot water bath</p> <p><u>Specifications:</u> Temperature: 40 to 45°C.</p>
2.	<p><u>Medium preparation:</u></p> <p>A. Using the hot water bath, melt the SPG Supposi-Base™.</p> <p><u>Specifications:</u> Maintain temperature between 40°C and 45°C.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>IMPORTANT: Do not allow the temperature to exceed 45°C.</p>
3.	<p><u>Medium integration:</u></p> <p>A. Triturate the Acetaminophen to form a fine, homogeneous powder.</p> <p>B. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:</p> <p>-Fine, homogeneous powder (Step 3A) -Silica Gel (Micronized)</p> <p>C. Using the hot water bath, incrementally add the homogeneous powder blend (Step 3B) to the melted SPG Supposi-Base™ (Step 2A).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques. Maintain temperature between 40°C and 45°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>



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4.	<p><u>Mold filling:</u></p> <p>A. Remove the mixture (Step 3C) from the heat. With continuous stirring, allow to cool slightly, until the mixture is thicker (with a lotion-like consistency).</p> <p>B. Fill the 30 mold cavities with the mixture. If the mixture starts to solidify, reheat to 40 – 45°C, and repeat the filling procedure.</p> <p>C. Once the cavities have been filled, allow the suppositories to cool to room temperature.</p> <p>D. If necessary, trim the tops of the suppositories with a sharp blade or a hot spatula.</p>		
5.	<p><u>Validation technique:</u></p> <p>A. Weigh 6 suppositories separately.</p> <p>B. The final weight of each suppository from Step 5A (not including the weight of the suppository mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 1.36 g in accordance to USP guidelines.</p>		
6.	<p><u>Product transfer:</u></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		Packaging Requirements	
	6 months, refrigerated, as per USP*.		Individually wrapped in a tight, light-resistant foil and placed in a suppository box or wide-mouth container.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 For rectal use only.
	2	Keep out of reach of children.	7 Equilibrate to room temperature before use.
	3	Keep refrigerated. Do not freeze.	8 Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Cap tightly after use.	9 Keep in a dry place.
	5	Protect from light.	10 Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredient 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

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