



Suggested Formula	Diazepam 5 mg Rectal Suppositories (Solid Suspension, 100 x 1.3 mL Suppositories)	FIN	F 001 603v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Diazepam, USP	0.500	g				
Silica Gel	2.50	g				
Propylene Glycol, USP	5.0	mL				
Medisca Polypeg (Suppository base)	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance (adhere to proper handling and documentation procedures)

Diazepam

Light sensitive (protect from light whenever possible):

Diazepam, Propylene Glycol

Hygroscopic (protect from moisture whenever possible):

Silica Gel, Propylene Glycol

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.

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SUGGESTED PREPARATION (for 100 x 1.3 mL suppositories)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Diazepam, USP §	0.500	g			
Silica Gel §	2.50	g			
Propylene Glycol, USP §	5.0	mL			
Medisca Polypeg (Suppository base)	TBD				

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

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<u>Preparatory step:</u> A. Prepare a hot water bath <u>Specifications:</u> Temperature: 60 to 65°C.
2.	<u>Ingredient quantification (mold calibration):</u> Calculate the quantity of Polypeg (Suppository Base) required for 100 suppositories. Refer to the Appendix for details.

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3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none">- Diazepam- Silica Gel <p>B. Levigate the fine, homogeneous powder blend (Step 3A) with the following ingredient:</p> <ul style="list-style-type: none">- Propylene Glycol <p><u>End result:</u> Homogeneous paste-like dispersion.</p>
4.	<p><u>Medium preparation:</u></p> <p>A. Using the hot water bath, melt the following ingredient:</p> <ul style="list-style-type: none">- Polypeg (Suppository base) (amount determined from Appendix, Step 7B) <p><u>Specifications:</u> Maintain temperature between 60 and 65°C</p> <p><u>End result:</u> Homogeneous liquid-like solution</p> <p>IMPORTANT: Do not allow the temperature to exceed 65°C.</p>

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5.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Using the hot water bath, incrementally add the homogeneous paste-like dispersion (Step 3B) to the following ingredient:</p> <ul style="list-style-type: none">- Homogeneous liquid-like solution (Step 4A). <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60 and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p>IMPORTANT: Do not add the homogeneous paste-like dispersion (Step 3B) until the temperature of the Polypeg reaches 60 - 65°C. Do not allow the temperature to exceed 65°C.</p>
6.	<p><u>Mold filling:</u></p> <p>A. Remove the homogeneous liquid-like dispersion (Step 5A) from the hot water bath. With continuous stirring, allow to cool slightly, until the mixture is thicker (with a lotion-like consistency).</p> <p>B. Fill each of 100 mold cavities with the mixture. If the mixture starts to solidify, reheat to 60 - 65°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>
7.	<p><u>Validation technique (average solid dose weight):</u></p> <p>A. Weigh 20 suppositories.</p> <p>B. The final weight of each suppository (not including suppository mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight for each unit (Appendix, Step 7A) in accordance to USP guidelines.</p>
8.	<p><u>Product transfer (solid-to-dispensing container filling):</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	30 days, refrigerated.	Packaging Requirements	Individually wrapped in a tight, light-resistant foil and placed in a box or wide-mouth container.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	Protect from light.
	2	Keep out of reach of children.	8	Keep in a dry place.
	3	For rectal use only.	9	Equilibrate to room temperature before use.
	4	Keep refrigerated. Do not freeze.	10	Controlled substance. Dangerous unless used as directed.
	5	Do not take with alcohol, sleep aids tranquilizers or other CNS depressants.	11	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	6	May impair mental and or physical ability. Use care when operating a car or machinery.	12	May produce psychological and/or physical dependence.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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7.	Diazepam. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 3rd Edition</i> . American Pharmaceutical Association; 2005: 138.
8.	Diazepam (Monograph). US Pharmacopeial Convention, Inc. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. 2004: 617.
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Appendix	Suppository mold calibration		
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SUGGESTED CALCULATION

Preparatory Instruction									
1.	<p><u>Preparatory step:</u></p> <p>A. Prepare a hot water bath</p> <p><u>Specifications:</u> Temperature: 60 to 65°C.</p>								
2.	<p><u>Vehicle preparation:</u></p> <p>Weigh and/or measure the following ingredients:</p> <table border="1"><thead><tr><th>Ingredient</th><th>Quantity</th></tr></thead><tbody><tr><td>Silica Gel</td><td>0.25 g</td></tr><tr><td>Propylene Glycol, USP</td><td>0.5 mL</td></tr><tr><td>Medisca Polypeg (Suppository Base)</td><td>14.32 g</td></tr></tbody></table>	Ingredient	Quantity	Silica Gel	0.25 g	Propylene Glycol, USP	0.5 mL	Medisca Polypeg (Suppository Base)	14.32 g
Ingredient	Quantity								
Silica Gel	0.25 g								
Propylene Glycol, USP	0.5 mL								
Medisca Polypeg (Suppository Base)	14.32 g								
3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Triturate the following ingredient to form a fine, homogeneous powder:</p> <ul style="list-style-type: none">- Silica Gel <p>B. Levigate the fine homogeneous powder (Step 3A) with following ingredient:</p> <ul style="list-style-type: none">- Propylene Glycol <p><u>End result:</u> Homogeneous paste-like dispersion.</p>								

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Appendix	Suppository mold calibration		
4.	<p><u>Medium preparation:</u></p> <p>A. Using the hot water bath, melt the following ingredient:</p> <ul style="list-style-type: none">- Polypeg (Suppository Base) <p><u>Specifications:</u> Maintain temperature between 60 and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>IMPORTANT: Do not allow the temperature to exceed 65°C.</p>		
5.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Using the hot water bath, incrementally add the homogeneous paste-like dispersion (Step 3B) to the following ingredient:</p> <ul style="list-style-type: none">- Homogeneous liquid-like solution (Step 4A). <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60 and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p>IMPORTANT: Do not add the homogeneous paste-like dispersion (Step 3B) until the temperature of the Polypeg reaches 60 - 65°C. Do not allow the temperature to exceed 65°C.</p>		
6.	<p><u>Mold filling:</u></p> <p>A. Remove the homogeneous liquid-like dispersion (Step 5A) from the hot water bath. With continuous stirring, allow to cool slightly, until the mixture is thicker (with a lotion-like consistency).</p> <p>B. Fill 5 mold cavities with the mixture. If the mixture starts to solidify, reheat to 60 - 65°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>		

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Appendix	Suppository mold calibration		
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7. **Ingredient calculation:**

A. Calculate the average weight of a suppository (not including weight of the empty suppository mold):

Weight of the 5 suppositories:	_____ g
DIVIDED BY	
Number of suppositories:	5
EQUALS	
Average (theoretical) weight of a suppository:	_____ g

B. Calculate the quantity of Polypeg (Suppository Base) contained in a single suppository:

Average weight of a suppository (from Step 7A):	_____ g
MINUS	
Combined quantity of Diazepam, Silica Gel and Propylene Glycol in each suppository:	0.082 g
EQUALS	
Quantity of Polypeg (Suppository Base) contained in a single suppository:	_____ g
MULTIPLIED BY	
Number of suppositories in batch	100
EQUALS	
Quantity of Polypeg (Suppository Base) required for 100 suppositories	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
Quantity of Polypeg (Suppository Base) required plus processing error	_____ g

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