



Suggested Formula	Amphetamine Aspartate 2.5 mg/5 mL, Amphetamine Sulfate 2.5 mg/5 mL, Dextroamphetamine Saccharate 2.5 mg/5 mL, Dextroamphetamine Sulfate 2.5 mg/5 mL Oral Suspension (Suspension, 150 mL)	FIN	F 003 206v4
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amphetamine Aspartate 2.5 mg/Amphetamine Sulfate 2.5 mg/Dextroamphetamine Saccharate 2.5 mg/Dextroamphetamine Sulfate 2.5 mg Tablets	30	Units				
Glycerin, USP	10.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	70.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 150.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance (adhere to proper handling and documentation procedures)

Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate

Hygroscopic (protect from moisture whenever possible): Glycerin

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 150 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : _____	Processing Error	Qty. to measure
Amphetamine Asparate 2.5 mg/Amphetamine Sulfate 2.5 mg/Dextroamphetamine Saccharate 2.5 mg/Dextroamphetamine Sulfate 2.5 mg Tablets	30	Units			
Glycerin, USP §	10.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	70.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 150.0	mL			

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

§ Weigh / measure just prior to use.





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Preparatory Instruction

1. Ingredient quantification (determine the actual quantity of Amphetamine/Dextroamphetamine tablet powder mix to weigh):

A. Weigh 33 Amphetamine/Dextroamphetamine Tablets. Record the total weight here: _____ g

B. Calculate the average weight of powder in each tablet:

Weight of 33 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets:	33
EQUALS	
Average weight of a single Amphetamine/Dextroamphetamine Tablet:	_____ g

C. Calculate the weight of powder equivalent to 30 tablets:

Average weight of a single Amphetamine/Dextroamphetamine Tablet (from Step 1B):	_____ g
MULTIPLIED BY	
Number of tablets required:	30
EQUALS	
Weight of powder equivalent to 30 tablets:	_____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 30 tablets (from Step 1C):	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required <i>plus</i> processing error adjustments:	_____ g



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2.	<p><u>Powder preparation:</u></p> <p>A. Crush and triturate the 33 Amphetamine/Dextroamphetamine Tablets into a fine homogeneous powder.</p> <p>B. Weigh the quantity of Amphetamine/Dextroamphetamine tablet powder mix required for the batch (refer to Step 1D) and discard the remaining powder.</p>		
3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Levigate the Amphetamine/Dextroamphetamine tablet powder mix (amount weighed in Step 2B) with the Glycerin.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p> <p>B. Incrementally add the homogeneous paste-like dispersion (Step 3A) to the Oral Suspend (Suspending Vehicle).</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><u>Filling to volume:</u></p> <p>A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 3B) to fill to the required batch size (150.0 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>		
5.	<p><u>Product transfer:</u></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 dispensing bottle. - To be administered with a metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.	7 Cap tightly after use.
	3	Shake well before use.	8 Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep refrigerated. Do not freeze.	9 Controlled substance. Dangerous unless used as directed.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	10 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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