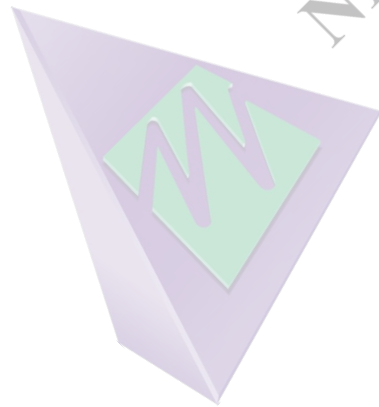




Suggested Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Atomoxetine hydrochloride, USP	0.500	g				
Purified water, USP	25.0	mL				
Methylcellulose 3% solution †	35.0	mL				
Raspberry flavor	2.0	mL				
Syrup, NF (Simple)	35.0	mL				
Syrup, NF (Simple)	qs to 100.0	mL				
Sodium hydroxide 1N solution	as needed					
† Methylcellulose 3% solution						
Methylcellulose, USP (1500 CPS)	1.50	g				
Purified water, USP	50.0	mL				



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Suggested Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible):

Atomoxetine hydrochloride

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

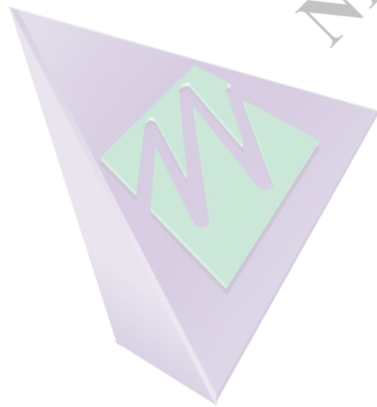
Processing Error /
Testing Considerations:

To account for processing error and pH testing considerations during preparation, it is suggested to measure an additional **2 to 3%** 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 Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
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SUGGESTED PREPARATION (for 100 mL liquid)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Atomoxetine hydrochloride, USP (§)	0.500	g			
Purified water, USP	25.0	mL			
Methylcellulose 3% solution †	35.0	mL			
Raspberry flavor	2.0	mL			
Syrup, NF (Simple)	35.0	mL			
Syrup, NF (Simple)	qs to 100.0	mL			
Sodium hydroxide 1N solution	as needed				
† Methylcellulose 3% solution concentrate					
Methylcellulose, USP (1500 CPS)	1.50	g			
Purified water, USP	50.0	mL			

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

§ Weigh / measure just prior to use.

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Suggested Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
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Preparatory Instruction

1.	<p><u>Methylcellulose 3% solution preparation:</u></p> <p>A. Heat 40 mL of purified water to 50-60 °C.</p> <p>B. With continuous stirring, add methylcellulose to the heated water (Step A).</p> <p>C. Stir for 5 minutes and allow for solution to cool down to room temperature.</p> <p>D. With continuous mixing, add cold purified water to a final volume of 50.0 mL.</p> <p><u>Note:</u> Keep mixing until a clear, homogeneous solution is obtained</p>
2.	<p><u>Powder-liquid integration:</u></p> <p>With stirring, incrementally add the following ingredients to the Purified water (25.0 mL plus processing error adjustments). Continue stirring until all of the solid particles have completely dissolved:</p> <ul style="list-style-type: none">- Atomoxetine hydrochloride <p>With stirring, incrementally add the following ingredients to the Atomoxetine hydrochloride solution. Continue stirring until homogeneously dispersed:</p> <ul style="list-style-type: none">- Methylcellulose 3% solution (35.0 mL plus processing error adjustments)- Syrup (35.0 mL plus processing error adjustments)- Raspberry flavor

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Suggested Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
3.	<u>pH testing:</u> A. Draw an appropriate amount of the final mixture. B. Test the pH of the sample. It should lie between 5.5 and 6.5. C. <u>If the pH < 5.5, carefully add the Sodium hydroxide solution to the mixture:</u> 1. Draw and transfer 1 or 2 drops of the Sodium hydroxide solution to the mixture. 2. Stir for at least 5 minutes to evenly disperse the Sodium hydroxide. 3. Re-test the pH. 4. Continue to add the Sodium hydroxide solution until the pH of 5.5 to 6.5 is obtained. IMPORTANT: Do not allow the pH to rise above 6.5.		
4.	<u>Filling to volume:</u> Add Syrup to the mixture to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments). Stir until homogeneous.		
5.	<u>Product transfer (dispensing container filling):</u> Transfer the final product into the specified dispensing container (see "Packaging requirements").		

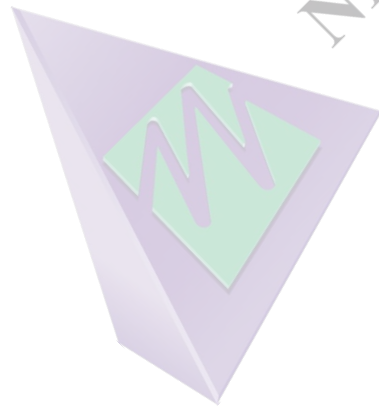
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Suggested Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated	Packaging Requirements	Light-resistant dispensing bottle	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4	Protect from light.
	2	Keep out of reach of children.	5	
	3	Keep refrigerated. Do not freeze.	6	
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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Suggested Formula	Atomoxetine hydrochloride 5 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 553
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