

## COMPOUND EVALUATION FORM

<b>Compound Name:</b> Amiodarone	<b>Container-closure system(s):</b> tight, light resistant container
<b>Strength:</b> 5 mg/mL	<b>Preservatives:</b> preservatives contained in Ora Blend
<b>Dosage Form:</b> Oral Suspension	<b>Beyond Use Date (compound type):</b> 90 days refrigerated
<b>Product Description:</b> Opaque Suspension	<b>Storage:</b> Refrigeration preferred
<b>Auxiliary Labels:</b> Shake Well, Refrigerate	
<b>Quality control procedures (ex: pH test, etc.):</b> pH testing, visual inspection of the final product	
<b>Ingredients:</b> Amiodarone 200 mg tablets Sodium Bicarbonate Powder Sterile Water for Irrigation Ora-Blend (QS) final product	

**Instructions for preparation:**

1. Weigh out sodium bicarbonate powder and place in graduate.
2. Add sufficient sterile water for irrigation to graduate containing sodium bicarbonate powder to prepare a sodium bicarbonate 50 mg/mL solution. Stir well to ensure powder is fully dissolved.
3. Measure an amount of Ora Blend equal to anticipated final product volume in a graduated cylinder. Add small amounts of the sodium bicarbonate solution prepared in step 2 and stir well to adjust the pH of Ora Blend to create a buffered suspension. The buffered suspension must have a final pH =  $6.5 \pm 0.5$ .
4. Crush tablets in a mortar and triturate into a fine powder with a pestle.
5. Wet powder with a minimal amount of buffered suspension and levigate to form a viscous, but smooth and uniform paste.
6. Continue adding suspension geometrically, mixing well after each addition.

**Calculations:**

<b>Ingredient Name/Strength/Form</b>	<b>QS</b>	<b>Quantity</b>	<b>Units</b>
Amiodarone 200 mg tablets		5	tablets
Sodium Bicarbonate Powder		3	grams
Sterile Water for Irrigation		60	mL
Ora Blend	X	200	mL

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7. QS to final volume with buffered suspension. Foaming may occur during preparation, allow the product to settle for 10 minutes and perform an additional QS if necessary. Any excess buffered suspension may be discarded.

Notes: Suspension will clump if buffer is not added.

**Equipment/ Supplies:**

<input checked="" type="checkbox"/> Mortar and Pestle	<input checked="" type="checkbox"/> Stirring rod	<input type="checkbox"/> Ointment slab
<input checked="" type="checkbox"/> Graduated cylinder(s)	<input type="checkbox"/> Spatula	<input type="checkbox"/> Balance
<input type="checkbox"/> Weigh paper	<input checked="" type="checkbox"/> Amber (plastic/glass) bottle	<input type="checkbox"/> Ointment jar
<input checked="" type="checkbox"/> Counting tray	<input type="checkbox"/> Syringe	<input type="checkbox"/> Funnel
		<input checked="" type="checkbox"/> pH meter

**References:**

USP. Amiodarone Hydrochloride Oral Suspension In: USP–NF. Rockville, MD: USP; June 2022

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