

## COMPOUND EVALUATION FORM

<b>Compound Name:</b> Amiodarone	<b>Container-closure system(s):</b> Plastic or Glass Amber Bottle
<b>Strength:</b> 5 mg/mL	<b>Preservatives:</b> Ora-Blend
<b>Dosage Form:</b> Oral Suspension	<b>Beyond Use Date (compound type):</b> 42 days (Room Temperature) or 90 days (Refrigerate)
<b>Product Description:</b> Opaque Suspension	<b>Storage:</b> Refrigerate (preferred) or room temperature
<b>Auxiliary Labels:</b> Shake Well; Refrigerate	
<b>Quality control procedures (ex: pH test, etc.):</b> pH test	
<b>Ingredients:</b> Amiodarone 200 mg tablets Ora-Blend SF (1:1 Ora-Plus/Ora-Sweet) Sodium Bicarbonate 8.4%	

**Instructions for preparation:****Calculations:**

1. Crush tablets in a mortar and pestle and triturate to a fine powder.
2. Mix the Ora-Blend with sufficient volume of sodium bicarbonate 8.4% to buffer to pH=6 to 7.  
 \*\*The pH of Ora-Blend varies by lot. The pH must be titrated to 6 to 7 and checked with a pH strip or meter for every batch.  
 DO NOT use a predetermined amount of sodium bicarbonate. The volume listed is an estimate. More or less may be needed.\*\*
3. Wet powder with a minimal amount of buffered suspension and levigate to form a viscous, but smooth and uniform paste.
4. Continue adding suspension geometrically, mixing well after each addition.
5. QS to final volume with buffered vehicle.

Notes: DO NOT use all the buffered suspending mixture.  
 You must QS to final volume.  
 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

Revised: A Swick 04/2020



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X Counting tray

☐ Syringe

X pH meter

**References:**

1. Nahata MC, Morosco RS, Hipple TF. Stability of Amiodarone in Extemporaneous Oral Suspensions Prepared from Commercially Available Vehicles. *Journal of Pediatric Pharmacy Practice*. 1999;4:186-189.

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