

## Amiodarone Hydrochloride Suspension 5 mg/mL— Formulation 1\*

### INGREDIENTS:

Amiodarone hydrochloride 200 mg tablet	3 tablets
Sodium bicarbonate solution*	QS to pH 6–7
Ora-Plus/Ora-Sweet*	QSAD: 120 mL

### EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, mortar and pestle, graduated cylinder, 5-mL oral syringe

### PREPARATION DETAILS:

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Levigate powder with a small amount of vehicle to form a paste.
3. Add vehicle in increasing amounts while mixing thoroughly.
4. Transfer contents of the mortar to a graduated cylinder.
5. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
6. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
7. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
8. Shake well to mix.

**Special Instructions** — \*Mix 60 mL of Ora-Plus with 60 mL of Ora-Sweet or use Ora-Blend. Sodium bicarbonate solution is prepared by mixing 5 g of sodium bicarbonate powder in 100 mL distilled water. Use sodium bicarbonate solution to adjust pH of Ora-Plus and Ora-Sweet mixture or Ora-Blend to 6–7. Use mixture as vehicle.

**Alternatives** — May substitute vehicle with 60 mL of Ora-Plus mixed with 60 mL of Ora-Sweet SF or Ora-Blend SF and adjust pH to 6–7 with sodium bicarbonate solution as listed above or with 60 mL of methylcellulose 1% (see page 107 for preparation directions) mixed with 60 mL of simple syrup NF.

**Quality-Control Procedures** — Conduct pH testing to adjust for a pH of 6–7. Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

**Labeling Requirements** — Extemporaneously compounded preparation. For oral use only. Store at room temperature or refrigerate. Shake well before use.

**Storage Conditions/Stability** — Store at room temperature or refrigerate. Stable for 91 days when refrigerated or 42 days when stored at room temperature.

### STABILITY STUDY DETAILS:

**Study Container Type** — Plastic bottle (for all vehicles), glass bottle (for methylcellulose/simple syrup NF as vehicle only)

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## Amiodarone Hydrochloride Suspension 5 mg/mL— Formulation 1\* (continued)

**Referenced Manufacturers** — Amiodarone hydrochloride tablets (Cordarone, Wyeth-Ayerst Laboratories); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC); methylcellulose (not specified); simple syrup (Humco); sodium bicarbonate powder (JT Baker Inc); distilled water (not specified).

**Stability-Indicating Study** — Yes

### REFERENCES

1. Nahata MC, Morosco RS, Hipple TF. Stability of amiodarone in extemporaneous oral suspensions prepared from commercially available vehicles. *J Pediatr Pharm Pract.* 1999;4:186-189.
2. Nahata MC. Stability of amiodarone in an oral suspension stored under refrigeration and at room temperature. *Ann Pharmacother.* 1997;31(7-8):851-852.