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Amiodarone Hydrochloride Compounded Oral Suspension

DEFINITION

Amiodarone Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of amiodarone hydrochloride ($C_{25}H_{29}I_2NO_3 \cdot HCl$).

Prepare Amiodarone Hydrochloride Compounded Oral Suspension 5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Amiodarone Hydrochloride tablets[a] equivalent to	600 mg of amiodarone hydrochloride
Vehicle: a 1:1 mixture of Ora-Sweet[b] (regular or sugar-free) and Ora-Plus,[b] a sufficient quantity to make	120 mL

[a] Cordarone 200-mg tablets, Wyeth-Ayerst Laboratories, Philadelphia, PA.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Amiodarone Hydrochloride tablets* in a suitable mortar and comminute to a fine powder with a pestle. Adjust the pH of the *Vehicle* to 6.5 ± 0.5 with a sodium bicarbonate 50-mg/mL solution prepared in Purified Water. Add the *Vehicle* in small portions and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make an amiodarone hydrochloride liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume and mix well.

ASSAY

• **Procedure**

Mobile phase: Methanol, water, and 50 mM monobasic ammonium phosphate (0.5:0.5:99)

Standard solution: 2.5 mg/mL of USP Amiodarone Hydrochloride RS in *Mobile phase*

Sample solution: Shake thoroughly by hand each bottle of the Oral Suspension. Prepare 2.5 mg/mL of amiodarone hydrochloride from Oral Suspension and *Mobile phase*.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 10-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for amiodarone is about 3.6 min.]

Suitability requirements

Relative standard deviation: NMT 2.1% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amiodarone hydrochloride ($C_{25}H_{29}I_2NO_3 \cdot HCl$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Amiodarone Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of amiodarone hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.8–6.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator; NMT 30 days when stored at controlled room temperature

• **Labeling:** Label it to state that it is to be well shaken before use and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩
USP Amiodarone Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMIODARONE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

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