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Amiodarone Hydrochloride Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-amiodarone-hcl-tabs-20210129>.

DEFINITION

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

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: Add 3 mL of [acetic acid, glacial](#) to 1 L of [water](#). Adjust with [ammonia water, 25 percent](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (40:60)

Standard solution: 0.1 mg/mL of [USP Amiodarone Hydrochloride RS](#) in *Mobile phase*

Sample stock solution: Nominally 1 mg/mL of amiodarone hydrochloride in *Mobile phase* prepared as follows. Transfer a quantity, equivalent to 100 mg of amiodarone hydrochloride, from NLT 20 finely powdered Tablets to a 100-mL volumetric flask. Add *Mobile phase* to about 50% of the final flask volume. Sonicate with occasional shaking to dissolve. Cool the solution and dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.1 mg/mL of amiodarone hydrochloride in *Mobile phase* from *Sample stock solution*. Pass a portion of the solution through a suitable filter of 0.45-μm pore size, discard the first few milliliters, and collect the filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 240 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 2.5 times the retention time of amiodarone

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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 Tablets taken:

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

r_U = peak response of amiodarone from the *Sample solution*

r_S = peak response of amiodarone 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%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1**Medium:** 1% (w/v) [sodium dodecyl sulfate](#); 1000 mL**Apparatus 2:** 100 rpm**Time:** 60 min**Standard stock solution:** 0.2 mg/mL of [USP Amiodarone Hydrochloride RS](#) prepared as follows. Transfer an appropriate quantity of [USP Amiodarone Hydrochloride RS](#) to a suitable volumetric flask and add [methanol](#) to 5% of the final flask volume. Sonicate to dissolve and dilute with *Medium* to volume.**Standard solution:** 0.01 mg/mL of [USP Amiodarone Hydrochloride RS](#) in *Medium* from *Standard stock solution***Sample solution:** Dilute a portion of the solution under test with *Medium* to a concentration similar to that of the *Standard solution*. Pass a portion of the solution through a suitable filter of 0.45-μm pore size, discard the first few milliliters, and collect the filtrate.**Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 243 nm**Cell:** 1 cm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of amiodarone hydrochloride ($C_{25}H_{29}I_2NO_3 \cdot HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

 A_U = absorbance of amiodarone from the *Sample solution* A_S = absorbance of amiodarone from the *Standard solution* C_S = concentration of [USP Amiodarone Hydrochloride RS](#) in the *Standard solution* (mg/mL) D = dilution factor for the *Sample solution* V = volume of *Medium*, 1000 mL L = label claim of amiodarone hydrochloride (mg/Tablet)**Tolerances:** NLT 80% (Q) of the labeled amount of amiodarone hydrochloride ($C_{25}H_{29}I_2NO_3 \cdot HCl$) is dissolved.**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium:** 0.2% (v/v) [polysorbate 80](#) in 0.05 N [hydrochloric acid](#) prepared as follows. Add 26 mL of [hydrochloric acid](#) and 12 mL of [polysorbate 80](#) to 6 L of deaerated [water](#); 900 mL.**Apparatus 2:** 75 rpm**Time:** 30 min**Standard solution:** 0.22 mg/mL of [USP Amiodarone Hydrochloride RS](#) prepared as follows. Transfer an appropriate quantity of [USP Amiodarone Hydrochloride RS](#) to a suitable volumetric flask, and add [methanol](#) to 20% of the final flask volume. Sonicate to dissolve and dilute with *Medium* to volume.**Sample solution:** Pass a portion of the solution through a suitable filter of 0.45-μm pore size, discard the first few milliliters, and collect the filtrate.**Instrumental conditions****Mode:** UV**Analytical wavelength:** 244 nm**Cell:** 0.1 cm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of amiodarone hydrochloride ($C_{25}H_{29}I_2NO_3 \cdot HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

 A_U = absorbance of amiodarone from the *Sample solution* A_S = absorbance of amiodarone from the *Standard solution* C_S = concentration of [USP Amiodarone Hydrochloride RS](#) in the *Standard solution* (mg/mL) V = volume of *Medium*, 900 mL L = label claim of amiodarone hydrochloride (mg/Tablet)