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Amodiaquine Hydrochloride Tablets

DEFINITION

Amodiaquine Hydrochloride Tablets contain an amount of amodiaquine hydrochloride ($C_{20}H_{22}ClN_3O \cdot 2HCl \cdot 2H_2O$) equivalent to NLT 93.0% and NMT 107.0% of the labeled amount of amodiaquine ($C_{20}H_{22}ClN_3O$).

IDENTIFICATION

Change to read:

- A.**  [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)  (CN 1-MAY-2020)

Sample: Powder 1 or more Tablets, and transfer a portion of the powder, equivalent to 50 mg of amodiaquine, to a 125-mL separator. Add 20 mL of water, and shake for 1 min. Add 25 mL of chloroform and 1 mL of ammonium hydroxide, shake for 2 min, and when settled, filter the chloroform extract through cotton that previously has been rinsed with chloroform, collecting the extract in a vessel suitable for evaporation. Evaporate the chloroform, and dry the residue at 105° for 1 h.

Acceptance criteria: Meet the requirements

- B.** The retention time of the amodiaquine hydrochloride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Add 1.0 mL of perchloric acid to each 1 L of solution, adjust with phosphoric acid to a pH of 2.5, and pass through a filter of 0.45-µm pore size.

Diluent: 1% (v/v) hydrochloric acid in water

Mobile phase: Methanol and *Buffer* (22:78)

Standard solution: 0.15 mg/mL of [USP Amodiaquine Hydrochloride RS](#) and 0.15 mg/mL of [USP Chloroquine Phosphate RS](#) in water

Sample solution: Transfer a quantity equivalent to 7.5 mg of amodiaquine hydrochloride from finely powdered Tablets (NLT 20) to a 50-mL volumetric flask, and dissolve in and dilute with *Diluent* to volume. Sonicate for 25 min at 29°. Pass 10 mL through a nylon filter of 0.2-µm pore size, discarding the first 4 mL. Use 2 mL for the analysis.

Chromatographic system

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

Mode: LC

Detector: UV 224 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for the chloroquine and amodiaquine peaks are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between amodiaquine hydrochloride and chloroquine phosphate

Tailing factor: NMT 1.5 for amodiaquine hydrochloride and chloroquine phosphate

Relative standard deviation: NMT 2.0% for amodiaquine hydrochloride and chloroquine phosphate

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amodiaquine ($C_{20}H_{22}ClN_3O$) in the portion of Tablets 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 amodiaquine in [USP Amodiaquine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

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

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Detector: UV 342 nm

Standard solution: [USP Amodiaquine Hydrochloride RS](#) in *Medium*

Sample solution: Filter portions of the solution under test, suitably diluted with water, if necessary, in comparison with a *Standard solution* having a known concentration of [USP Amodiaquine Hydrochloride RS](#).

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the amount of amodiaquine hydrochloride ($C_{20}H_{22}ClN_3O \cdot 2HCl \cdot 2H_2O$) dissolved from UV absorbances.

Tolerances: An amount of amodiaquine hydrochloride ($C_{20}H_{22}ClN_3O \cdot 2HCl \cdot 2H_2O$) equivalent to NLT 75% (Q) of the labeled amount of amodiaquine ($C_{20}H_{22}ClN_3O$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Amodiaquine Hydrochloride RS](#)

[USP Chloroquine Phosphate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
AMODIAQUINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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