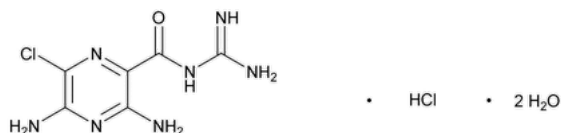


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Amiloride Hydrochloride

Change to read:



$C_6H_8ClN_7O \cdot HCl \cdot 2H_2O$ 302.12

Pyrazinecarboxamide, 3,5-diamino-*N*-(aminoiminomethyl)-6-chloro-, monohydrochloride dihydrate;

N-Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride dihydrate;

▲3,5-Diamino-*N*-carbamidoyl-6-chloropyrazine-2-carboxamide hydrochloride dihydrate▲ (USP 1-Aug-2022) CAS RN®: 17440-83-4; UNII: FZJ37245UC.

▲Amiloride hydrochloride (anhydrous)

$C_6H_8ClN_7O \cdot HCl$ 266.09 CAS RN®: 2016-88-8; UNII: 7M458Q65S3.

Amiloride (free base)

$C_6H_8ClN_7O$ 229.63 CAS RN®: 2609-46-3; UNII: 7DZO8EB0Z3.▲ (USP 1-Aug-2022)

Change to read:

DEFINITION

Amiloride Hydrochloride contains NLT 98.0% and NMT ▲102.0%▲ (USP 1-Aug-2022) of amiloride hydrochloride ($C_6H_8ClN_7O \cdot HCl$), calculated on the ▲anhydrous▲ (USP 1-Aug-2022) basis.

IDENTIFICATION

Change to read:

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197M ▲or 197A▲ (USP 1-Aug-2022)

Change to read:

• **B.** ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP

1-Aug-2022)

• **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#): Meets the requirements

ASSAY

Change to read:

• PROCEDURE

▲**Mobile phase:** Dissolve 0.8 g of [sodium 1-hexanesulfonate, monohydrate](#) in 900 mL of [water](#). Add 100 mL of [acetonitrile](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

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

Sample solution: 0.1 mg/mL of Amiloride Hydrochloride in *Mobile Phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.0-mm × 12.5-cm; 5-μm packing [L7](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μL

Run time: NLT 2 times the retention time of amiloride

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of amiloride hydrochloride ($C_6H_8ClN_7O \cdot HCl$) in the portion of Amiloride Hydrochloride taken:

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

 r_U = peak response of amiloride from the *Sample solution* r_S = peak response of amiloride from the *Standard solution* C_S = concentration of [USP Amiloride Hydrochloride RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Amiloride Hydrochloride in the *Sample solution* (mg/mL)▲ (USP 1-Aug-2022)**Acceptance criteria:** 98.0%–▲102.0%▲ (USP 1-Aug-2022) on the ▲anhydrous▲ (USP 1-Aug-2022) basis**IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:• **ORGANIC IMPURITIES**▲**Mobile phase** and **Chromatographic system:** Proceed as directed in the Assay.**Standard solution:** 1 µg/mL each of [USP Amiloride Hydrochloride RS](#) and [USP Amiloride Related Compound A RS](#) in *Mobile phase***Sensitivity solution:** 0.5 µg/mL each of [USP Amiloride Hydrochloride RS](#) and [USP Amiloride Related Compound A RS](#) in *Mobile phase*, from *Standard solution***Sample solution:** 1 mg/mL of Amiloride Hydrochloride in *Mobile phase***System suitability****Samples:** *Standard solution* and *Sensitivity solution***Suitability requirements****Relative standard deviation:** NMT 5.0% for amiloride and amiloride related compound A, *Standard solution***Signal-to-noise ratio:** NLT 10 for amiloride and amiloride related compound A, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of amiloride related compound A in the portion of Amiloride Hydrochloride taken:

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

 r_U = peak response of amiloride related compound A from the *Sample solution* r_S = peak response of amiloride related compound A from the *Standard solution* C_S = concentration of [USP Amiloride Related Compound A RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Amiloride Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of amiloride acid, 5-hydroxyamiloride, and any unspecified impurity in the portion of Amiloride Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

 r_U = peak response of amiloride acid, 5-hydroxyamiloride, or any unspecified impurity from the *Sample solution* r_S = peak response of amiloride from the *Standard solution* C_S = concentration of [USP Amiloride Hydrochloride RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Amiloride Hydrochloride in the *Sample solution* (mg/mL) F = relative response factor (see [Table 1](#))**Acceptance criteria:** See [Table 1](#). The reporting threshold is 0.05%.**Table 1**