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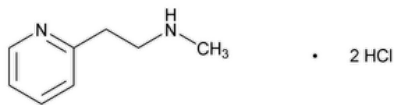
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Betahistine Hydrochloride


 $C_8H_{12}N_2 \cdot 2HCl$ 209.12

2-Pyridineethanamine, N-methyl-, dihydrochloride;

2-[2-(Methylamino)ethyl]pyridine, dihydrochloride CAS RN®: 5579-84-0.

DEFINITION

Betahistine Hydrochloride contains NLT 99.0% and NMT 101.0% of betahistine hydrochloride ($C_8H_{12}N_2 \cdot 2HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Meets the requirements.

- B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#): Meets the requirements

ASSAY

PROCEDURE

Solution A: 0.69 mg/mL of [ammonium acetate](#) in [water](#). Adjust with [glacial acetic acid](#) to a pH of 4.7.Mobile phase: [Acetonitrile](#) and *Solution A* containing 2.88 mg/mL of [sodium lauryl sulfate](#) (7:13)Standard solution: 0.38 mg/mL of [USP Betahistine Hydrochloride RS](#) in *Mobile phase*Sample solution: 0.38 mg/mL of Betahistine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.0-mm × 15-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 0.5 mL/min

Injection volume: 10 μL

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 betahistine hydrochloride ($C_8H_{12}N_2 \cdot 2HCl$) in the portion of Betahistine Hydrochloride taken:

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

 r_U = peak response of betahistine from the *Sample solution*
 r_S = peak response of betahistine from the *Standard solution*

C_S = concentration of [USP Betahistine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Betahistine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES

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

Solution A, Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Betahistine Hydrochloride taken:

$$\text{Result} = (r_U/r_T) \times 1/F \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of all the peak responses from the *Sample solution*

F = relative response factor of each impurity (see [Table 1](#)); 1.0 for all other peaks

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
2-(2-Hydroxyethyl) pyridine ^a	0.3	1.5	0.2
2-Vinylpyridine ^a	0.4	2.0	0.2
<i>N</i> -Methyl- <i>N,N</i> -bis(2-pyridin-2-yl-ethyl) amine ^b	2.4	1.1	0.2
Any unspecified impurity	—	—	0.10
Total impurities	—	—	0.5

^a This impurity is a hydrochloride salt.

^b This impurity exists as a trihydrochloride.

SPECIFIC TESTS

- [pH \(791\)](#).

Sample: 100 mg/mL of Betahistine Hydrochloride in [water](#)

Acceptance criteria: 2.0–3.0

- [LOSS ON DRYING \(731\)](#).

Analysis: Dry between 100° and 105° to constant weight.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

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

Topic/Question	Contact	Expert Committee
BETAHISTINE HYDROCHLORIDE	Documentary Standards Support	SM62025 Small Molecules Therapeutic Areas 6
REFERENCE STANDARDS SUPPORT	RS Technical Services RSTECH@usp.org	SM62025 Small Molecules Therapeutic Areas 6

Chromatographic Database Information: [Chromatographic Database](#)

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