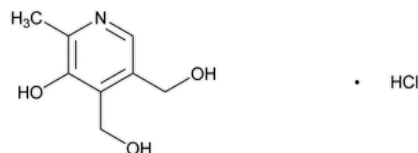


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Pyridoxine Hydrochloride



$C_8H_{11}NO_3 \cdot HCl$ 205.64

3,4-Pyridinedimethanol, 5-hydroxy-6-methyl-, hydrochloride;

Pyridoxol hydrochloride CAS RN®: 58-56-0; UNII: 68Y4CF58BV.

DEFINITION

Pyridoxine Hydrochloride contains NLT 98.0% and NMT 102.0% of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (CN 1-May-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Mix 10 mL of glacial acetic acid, 0.6 g of sodium 1-hexanesulfonate, and 700 mL of water in a 1000-mL volumetric flask.

Adjust with glacial acetic acid or 1 N sodium hydroxide to a pH of 3.0. Add 235 mL of methanol, and dilute with water to volume.

Internal standard solution: 5 mg/mL of *p*-hydroxybenzoic acid in *Mobile phase*

Standard solution: Prepare a 0.5-mg/mL solution of [USP Pyridoxine Hydrochloride RS](#) in *Mobile phase*. Transfer 10.0 mL of this solution and 1.0 mL of *Internal standard solution* to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Sample solution: Prepare a 0.5-mg/mL solution of Pyridoxine Hydrochloride in *Mobile phase*. Transfer 10.0 mL of this solution and 1.0 mL of *Internal standard solution* to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for pyridoxine and *p*-hydroxybenzoic acid are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.5 between pyridoxine and *p*-hydroxybenzoic acid

Relative standard deviation: NMT 3.0% for the ratios of the pyridoxine peak area response to the internal standard peak area response

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$) in the portion of Pyridoxine Hydrochloride taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = internal standard ratio (peak response of pyridoxine/peak response of the internal standard) from the *Sample solution*

R_S = internal standard ratio (peak response of pyridoxine/peak response of the internal standard) from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

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

SPECIFIC TESTS

• CONTENT OF CHLORIDE

Sample: 500 mg of Pyridoxine Hydrochloride

Blank: 50 mL of methanol

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 50 mL of methanol. Add 5 mL of glacial acetic acid and 2–3 drops of eosin Y TS. Titrate with the *Titrant*.

Perform a *Blank* determination.

Calculate the percentage of chloride (Cl) in the *Sample* taken:

$$\text{Result} = \{(V_S - V_B) \times N \times F / W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 35.45 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 16.9%–17.6% on the dried basis

- [Loss on Drying \(731\)](#): Dry a sample in vacuum over silica gel for 4 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

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

[USP Pyridoxine Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
PYRIDOXINE HYDROCHLORIDE	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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