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Pyridoxine Hydrochloride Tablets

DEFINITION

Pyridoxine Hydrochloride Tablets contain NLT 95.0% and NMT 115.0% of the labeled amount of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$).

IDENTIFICATION

• **A. Reaction with Ferric Ion**

Sample: Equivalent to 100 mg of pyridoxine hydrochloride from a quantity of powdered Tablets

Analysis: Add 5 mL of water to the *Sample*. Shake the mixture, filter into a test tube, and add 2 or 3 drops of ferric chloride TS.

Acceptance criteria: An orange to deep red color is produced.

ASSAY

• **Procedure**

Buffer: Dissolve 16 g of ammonium chloride in 70 mL of water, add 16 mL of ammonium hydroxide, dilute with water to 100 mL, and filter.

Color reagent: 0.4 mg/mL of 2,6-dichloroquinone chlorimide in isopropyl alcohol. [Note—Store the solution in a refrigerator, and use within one month. Do not use the solution if it has become pink.]

Standard stock solution: 0.1 mg/mL of USP Pyridoxine Hydrochloride RS in 0.1 N hydrochloric acid. [Note—Keep the solution in an amber bottle, in a cool place.]

Standard solution: 10 µg/mL of USP Pyridoxine Hydrochloride RS from the *Standard stock solution* diluted with water. [Note—Prepare this solution daily as needed.]

Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer, with the aid of water, a portion of the powdered Tablets to a conical flask. Add 0.5 mL hydrochloric acid per each mg of the nominal amount of pyridoxine hydrochloride taken, then dilute with water to about 0.04 mg/mL, and heat on a steam bath until disintegration is complete. Cool, dilute with water to 10 µg/mL, and centrifuge a portion of the mixture.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: Visible

Analytical wavelength: 650 nm

Blank: Water

Analysis

Samples: *Standard solution* and *Sample solution*

Separately add 25.0 mL of isopropyl alcohol to 5 mL each of the *Standard solution* and the *Sample solution*. Transfer 5 mL of each of the resulting solutions to separate, glass-stoppered, 25-mL graduated cylinders or test tubes, and add in succession, mixing after each addition, 1.0 mL of *Buffer*, 1.0 mL of a 0.2-g/mL solution of sodium acetate, and 1.0 mL of water. Cool to 25°, add 1.0 mL of *Color reagent*, and shake vigorously for 10 s, accurately timed. Determine the absorbance 90 s after the addition of the *Color reagent*. Repeat the procedure both for the *Standard solution* and the *Sample solution*, but substitute 1.0 mL of a 50-mg/mL solution of boric acid solution for the 1.0 mL of water.

[Note—Make the reading promptly to avoid errors due to fading of the color.]

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

$$\text{Result} = (A_U - A_U')/(A_S - A_S') \times (C_S/C_U) \times 100$$

A_U = absorbance of *Sample solution* with water

A_U' = absorbance of *Sample solution* with boric acid

A_S = absorbance of *Standard solution* with water

A_S' = absorbance of *Standard solution* with boric acid

C_S = concentration of USP Pyridoxine Hydrochloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of pyridoxine hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 95.0%–115.0%

PERFORMANCE TESTS

• **Dissolution,** *Procedure for a Pooled Sample*⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: A mixture of methanol, glacial acetic acid, and water (27:1:73) containing 1.40 mg/mL of sodium 1-hexanesulfonate

Standard solution: Known concentration of USP Pyridoxine Hydrochloride RS in *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with *Medium* if necessary

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times D \times V/L) \times 100$$

r_U = peak area of pyridoxine from the *Sample solution*

r_S = peak area of pyridoxine from the *Standard solution*

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

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

Content uniformity

Standard solution: 10 µg/mL of USP Pyridoxine Hydrochloride RS in dilute hydrochloric acid (1 in 100)

Sample solution: Transfer 1 Tablet, finely powdered, to a 500-mL volumetric flask containing 300 mL of water, shake for 30 min, and dilute with water to volume. Filter a portion of the mixture, discarding the first 25 mL of the filtrate. Dilute an aliquot of the filtrate with dilute hydrochloric acid (1 in 100) to obtain 10 µg/mL of pyridoxine hydrochloride.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 290 nm

Cell: 1 cm

Blank: Dilute hydrochloric acid (1 in 100)

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the absorbances of the *Standard solution* and *Sample solution*.

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

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

L = label claim (mg/Tablet)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, protected from light.
- **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 TABLETS	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

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