

Pyridoxine hydrochloride

Meets USP 41-NF 36, EP 9.0, JP 17, BP 2016 and IP 2018 testing specifications

Product Code: TC039M

Product Description :

Molecular weight: 205.64

Molecular formula: $C_8H_{11}NO_3.HCl$

CAS No.: 58-56-0

Synonym : Vitamin B₆; Pyridoxal hydrochloride

Quality Control:

Appearance (USP)

White to practically white crystals or crystalline powder

Appearance (EP, BP, IP)

White or almost white, crystalline powder

Appearance (JP)

White to pale yellow, crystalline powder.

Solubility (USP)

Freely soluble in water, slightly soluble in alcohol, insoluble in ether

Solubility (EP, BP)

Freely soluble in water, slightly soluble in ethanol (96%)

Solubility (JP)

Freely soluble in water, slightly soluble in ethanol (99.5%), and practically insoluble in acetic anhydride and in acetic acid (100%)

Solubility (IP)

Freely soluble in water, slightly soluble in ethanol (95%), practically insoluble in chloroform and in ether

Melting point (JP)

~206°C, with decomposition

Melting point (EP, BP)

~205°C, with decomposition

Identification 1 (UV) : (JP)

Both spectra exhibit similar intensities of absorption at the same wavelengths

Identification A : FTIR (USP, IP)

Matches with the standard pattern

Identification A : UV (EP, BP)

Complies

Identification 2 : FTIR (JP)

Matches with the standard pattern

Identification B : Chloride (USP)

Meets the requirements

Identification B : FTIR (EP, BP)

Matches with the standard pattern

Identification B : UV (IP)

Complies

Identification 3 : Chloride (JP)

Complies

Identification C : TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

Identification C : HPLC (IP)

The principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.

Identification D : Chloride (EP, BP, IP)

Complies

Appearance of solution (EP, BP)

5% solution in water is clear and not more intensely coloured than reference solution Y7

Appearance of solution (IP)

5% solution in water is clear and not more intensely coloured than reference solution YS7

Clarity and color of solution (JP)

5% solution in water is clear and colorless

pH (5% in water at 25°C) : (EP, BP, IP)

2.40 - 3.00

pH (2% in water at 25°C) : (JP)

2.50 - 3.50

Heavy metals (JP, USP)

<= 0.0030%

Heavy metals (BP, IP)

<= 0.0020%

Sulfated ash (EP, BP, IP)

<= 0.10%

Residue on ignition (USP, JP)

<= 0.10%

Loss on drying (USP)

<= 0.50% (in vacuum over silica gel, 4 hr)

Loss on drying (JP)

<= 0.30% (in vacuum over silica gel, 4 hr)

Loss on drying (EP, BP, IP)

<= 0.50% (at 105°C, 2 hr)

Related substances : TLC (JP)

The spot other than the principal spot obtained from the sample solution is not more intense than the spot obtained from the standard solution.

Related substances (system suitability 1, HPLC) :**Resolution (USP)**

>= 2.5, between pyridoxine and p-hydroxybenzoic acid

Related substances (system suitability 2, HPLC) :**RSD (USP)**

<= 3.00%

Related substances (system suitability, HPLC) :**Resolution (EP, BP)**

>= 1.5, between the peaks due to impurities A and B

Related substances (system suitability, HPLC):**Resolution (IP)**

>= 1.5, between the peaks due to pyridoxine impurities A and B

Related substances : Impurity B, HPLC (EP, BP, IP)

<= 0.15%

Related substances : Unspecified impurities, for each impurity, HPLC (EP, BP, IP)

<= 0.10%

Related substances : Total impurities, HPLC (EP, BP, IP)

<= 0.20%

Content of chloride, on dried basis (USP)

16.90 - 17.60%

Assay (HPLC, on dried basis) : (USP)

98.00 - 102.00%

Assay (NT, on dried basis) : (EP, BP, IP)

99.00 - 101.00%

Assay (NT, on dried basis) : (JP)

98.00 - 101.00%

Storage and Shelf Life:

Store at 2 - 8°C away from bright light.

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision: 02/2022

Disclaimer :

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