

CERTIFICATE OF ANALYSIS

PO NUMBER: 2024000861

Product name: Vitamin B₆ (Pyridoxine Hydrochloride)

Batch No.: PH24057047

Manufacturing date	May 22, 2024	Reporting date	May 28, 2024
Retest date	May 21, 2028	Article No.	03103
Package	25 kg per drum	Package size	Φ360 × 420 (mm)
Ref. pharmacopoeia(s)	BP2024, USP2024	Quantity	1,500 kg

Test Item	Specification	Result
Appearance	A white or almost white crystalline powder	Comply
Melting point	About 205℃	204.6℃
Identification	B: IR absorption; D: Reaction (a) of chlorides	Comply
Appearance of solution	Clear, not more intense than Y ₇	Comply
pH	2.4 ~ 3.0	2.7
BP2024	Loss on drying	≤0.5%
	Sulphated ash	≤0.1%
	Related substances	
	- Impurity B	≤0.15%
	- Unspecified impurity	≤0.10%
	- Total impurities	≤0.2%
	- Disregard limit: 0.05%	
USP2024	Assay (on dry basis)	99.0% ~ 101.0%
	Identification	A: IR absorption; B: Test of chloride
	Loss on drying	≤0.5%
	Residue on ignition	≤0.1%
	Residual solvent - Ethanol	≤0.5%
	Chloride	16.9% ~ 17.6%
	Assay (on dry basis)	98.0% ~ 102.0%
Conclusion: <i>This batch complies with the specification of BP2024 and USP2024.</i>		
Remark: Preserve in a tightly closed container, protected from light.		

Reported by: 刘勤兴

Approved by: 陈庆峰

hydroxides; sparingly soluble in alcohol; slightly soluble in water, in chloroform, and in ether.

Protamine Sulfate Injection: Colorless solution, which may have the odor of a preservative.

Protriptyline Hydrochloride: White to yellowish powder. Is odorless, or has not more than a slight odor. Melts at about 168°. Freely soluble in water, in alcohol, and in chloroform; practically insoluble in ether.

Pseudoephedrine Hydrochloride: Fine, white to off-white crystals or powder, having a faint characteristic odor. Very soluble in water; freely soluble in alcohol; slightly soluble in chloroform.

Pseudoephedrine Sulfate: White crystals or crystalline powder. Is odorless. Freely soluble in alcohol.

Pullulan: White powder. Freely soluble in water; practically insoluble in dehydrated alcohol. *NF category:* Coating agent; plasticizer; polymer membrane; sequestering agent; suspending and/or viscosity-increasing agent; wetting and/or solubilizing agent; bulking agent; diluent; disintegrant; wet binder; capsule shell; film-forming agent.

Pumice: Very light, hard, rough, porous, grayish masses or gritty, grayish powder. Is odorless and tasteless, and is stable in air. Practically insoluble in water; is not attacked by acids.

Pyrantel Pamoate: Yellow to tan solid. Soluble in dimethyl sulfoxide; slightly soluble in dimethylformamide; practically insoluble in water and in methanol.

Pyrazinamide: White to practically white, odorless or practically odorless, crystalline powder. Sparingly soluble in water; slightly soluble in alcohol, in ether, and in chloroform.

Pyrethrum Extract: Pale yellow liquid having a bland, flowery odor. Soluble in mineral oil and in most organic solvents; insoluble in water. *Pyrethrins I* denotes the group containing pyrethrin 1, cinerin 1, and jasmolin 1; *Pyrethrins II* denotes the group containing pyrethrin 2, cinerin 2, and jasmolin 2.

Pyridostigmine Bromide: White or practically white, crystalline powder, having an agreeable, characteristic odor. Is hygroscopic. Freely soluble in water, in alcohol, and in chloroform; slightly soluble in solvent hexane; practically insoluble in ether.

Pyridoxine Hydrochloride: White to practically white crystals or crystalline powder. Is stable in air, and is slowly affected by sunlight. Its solutions have a pH of about 3. Freely soluble in water; slightly soluble in alcohol; insoluble in ether.

Pyrilamine Maleate: White, crystalline powder, usually having a faint odor. Its solutions are acid to litmus. Very soluble in water; freely soluble in alcohol and in chloroform; slightly soluble in ether and in benzene.

Pyrimethamine: White, odorless, crystalline powder. Slightly soluble in acetone, in alcohol, and in chloroform; practically insoluble in water.

Quazepam: Off-white to yellowish powder.

Quetiapine Fumarate: White to off-white crystalline powder. Soluble in 0.1 N hydrochloric acid; slightly soluble in water, in alcohol, and in methanol.

Quinapril Hydrochloride: White to off-white powder, with a pink cast at times. Freely soluble in aqueous solvents.

Quinidine Gluconate: White powder. Is odorless and has a very bitter taste. Freely soluble in water; slightly soluble in alcohol.

Quinidine Sulfate: Fine, needle-like, white crystals, frequently cohering in masses, or fine, white powder. Is odorless, and darkens on exposure to light. Its solutions are neutral or alkaline to litmus. Soluble in alcohol; sparingly soluble in chloroform; slightly soluble in water; insoluble in ether.

Quinine Sulfate: White, fine, needle-like crystals, usually lusterless, making a light and readily compressible mass. Is odorless. It darkens on exposure to light. Its saturated solution

is neutral or alkaline to litmus. Freely soluble in alcohol at 80°, and in a mixture of 2 volumes of chloroform and 1 volume of dehydrated alcohol; sparingly soluble in water at 100°; slightly soluble in water, in alcohol, and in chloroform; very slightly soluble in ether.

Racemethionine: Almost white, crystalline powder or small flakes. Sparingly soluble in water; very slightly soluble in alcohol. It dissolves in dilute acids and in dilute solutions of alkali hydroxides. It melts at about 270°. *NF category:* Antioxidant; pH modifier (acidifying agent/alkalizing agent/buffering agent); flavors and fragrance.

Racepinephrine: White to nearly white, crystalline, odorless powder, gradually darkening on exposure to light and air. With acids, it forms salts that are readily soluble in water, and the base may be recovered by the addition of ammonium hydroxide. Very slightly soluble in water and in alcohol; insoluble in ether, in chloroform, and in fixed and volatile oils.

Racepinephrine Hydrochloride: Fine, white, odorless powder. Darkens on exposure to light and air. Its solutions are acid to litmus. Melts at about 157°. Freely soluble in water; sparingly soluble in alcohol.

Raloxifene Hydrochloride: Almost white to pale yellow powder. Freely soluble in dimethylsulfoxide; slightly soluble to sparingly soluble in methanol; practically insoluble to very slightly soluble in water; practically insoluble in ether and in ethyl acetate.

Raltegravir Potassium: White to off-white powder. Soluble in water; slightly soluble in methanol; very slightly soluble in acetonitrile and in ethanol; insoluble in isopropyl alcohol.

Ramipril: White to almost white crystalline powder. Freely soluble in methanol; sparingly soluble in water.

Ranitidine Hydrochloride: White to pale yellow, crystalline, practically odorless powder. Is sensitive to light and moisture. Melts at about 140°, with decomposition. Very soluble in water; sparingly soluble in alcohol.

Regorafenib: White to pink or brownish powder. Sparingly soluble in acetone; slightly soluble in acetonitrile, in methanol, in ethanol, and in ethyl acetate; practically insoluble in water and in heptane.

Fully Hydrogenated Rapeseed Oil: White, waxy solid. Insoluble in water and in alcohol. *NF category:* Coating agent; stiffening agent.

Superglycerinated Fully Hydrogenated Rapeseed Oil: White solid. Insoluble in water and in alcohol. *NF category:* Coating agent; emulsifying agent; stiffening agent.

Purified Rayon: White, lustrous or dull, fine, soft, filamentous fibers, appearing under the microscope as round, oval, or slightly flattened translucent rods, straight or crimped, striate and with serrate cross-sectional edges. Is practically odorless and practically tasteless. Very soluble in ammoniated cupric oxide TS and in dilute sulfuric acid (3 in 5); insoluble in ordinary solvents.

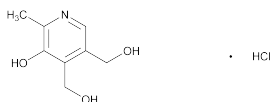
Repaglinide: White to off-white solid. Melts at about 132° to 136°. Soluble in methanol.

Reserpine: White or pale buff to slightly yellowish, odorless, crystalline powder. Darkens slowly on exposure to light, but more rapidly when in solution. Freely soluble in acetic acid and in chloroform; slightly soluble in benzene; very slightly soluble in alcohol and in ether; insoluble in water.

Resorcinol: White, or practically white, needle-shaped crystals or powder. Has a faint, characteristic odor and a sweetish, followed by a bitter, taste. Acquires a pink tint on exposure to light and air. Its solution (1 in 20) is neutral or acid to litmus. Freely soluble in water, in alcohol, in glycerin, and in ether; slightly soluble in chloroform.

Ribavirin: White, crystalline powder. Freely soluble in water; slightly soluble in dehydrated alcohol.

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.

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