

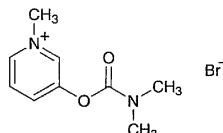
nation, and make any necessary correction.

Each mL of 0.05 mol/L sulfuric acid VS
= 12.311 mg of $C_5H_5N_3O$

Containers and storage Containers—Well-closed containers.

Pyridostigmine Bromide

臭化ピロドスチゲミン



$C_9H_{13}BrN_2O_2$: 261.12

3-Dimethylcarbamoyloxy-1-methyl-pyridinium bromide
[101-26-8]

Pyridostigmine Bromide, when dried, contains not less than 98.5% of $C_9H_{13}BrN_2O_2$.

Description Pyridostigmine Bromide occurs as a white, crystalline powder. It is odorless or has a slightly characteristic odor.

It is very soluble in water, freely soluble in ethanol (95) and in acetic acid (100), and practically insoluble in diethyl ether.

The pH of a solution of Pyridostigmine Bromide (1 in 10) is between 4.0 and 6.0.

It is deliquescent.

Identification (1) Dissolve 0.02 g of Pyridostigmine Bromide in 10 mL of water, add 5 mL of Reinecke salt TS: a light red precipitate is produced.

(2) To 0.1 g of Pyridostigmine Bromide add 0.6 mL of sodium hydroxide TS: the unpleasant odor of dimethylamine is perceptible.

(3) Determine the absorption spectrum of a solution of Pyridostigmine Bromide in 0.1 mol/L hydrochloric acid TS (1 in 30,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(4) A solution of Pyridostigmine Bromide (1 in 50) responds to the Qualitative Tests for Bromide.

Melting point 153 – 157°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Pyridostigmine Bromide in 10 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Pyridostigmine Bromide according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Pyridostigmine Bromide according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(4) Related substances—Dissolve 0.10 g of Pyridostigmine Bromide in 10 mL of ethanol (95), and use this solu-

tion as the sample solution. Pipet 2 mL of the sample solution, and add ethanol (95) to make exactly 10 mL. Pipet 1 mL of this solution, add ethanol (95) to make exactly 25 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of methanol, chloroform and ammonium chloride TS (5:4:1) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution in color.

Loss on drying Not more than 2.0% (1 g, in vacuum, phosphorus (V) oxide, 100°C, 5 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.3 g of Pyridostigmine Bromide, previously dried, dissolve in 10 mL of acetic acid (100), add 40 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

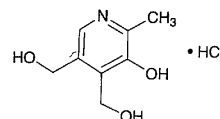
Each mL of 0.1 mol/L perchloric acid VS
= 26.112 mg of $C_9H_{13}BrN_2O_2$

Containers and storage Containers—Hermetic containers.

Pyridoxine Hydrochloride

Vitamin B₆

塩酸ピロドキシニン



$C_8H_{11}NO_3 \cdot HCl$: 205.64

5-Hydroxy-6-methylpyridine-3,4-dimethanol
monohydrochloride [58-56-0]

Pyridoxine Hydrochloride, when dried, contains not less than 98.0% of $C_8H_{11}NO_3 \cdot HCl$.

Description Pyridoxine Hydrochloride occurs as a white to pale yellow, crystalline powder. It is odorless, and has a bitter, acid taste.

It is freely soluble in water, slightly soluble in ethanol (95), and practically insoluble in acetic acid (100), in acetic anhydride and in diethyl ether.

The pH of a solution of Pyridoxine Hydrochloride solution (1 in 50) is between 2.5 and 3.5.

It is gradually affected by light.

Melting point: about 206°C (with decomposition).

Identification (1) To 1 mL of a solution of Pyridoxine Hydrochloride (1 in 1000) add 1 drop of iron (III) chloride TS: an orange-brown color is produced. Then add 1 drop of hydrochloric acid to the solution: the color changes to yellow.