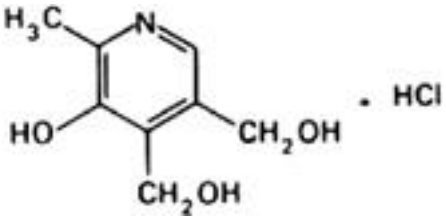
Pyridoxine hydrochloride (Pyridoxini hydrochloridum)

2018-01

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

Relative molecular mass. 205.6

Graphic formula.



Chemical name. 5-Hydroxy-6-methyl-3,4-pyridinedimethanol hydrochloride; 3-hydroxy-4,5-bis(hydroxymethyl)-2-methylpyridine hydrochloride; CAS Reg. No. 58-56-0.

Description. Colourless crystals or a white, crystalline powder; odourless.

Solubility. Freely soluble in water; slightly soluble in ethanol (~750 g/l) TS; practically insoluble in ether R.

Category. Vitamin.

Storage. Pyridoxine hydrochloride should be kept in a tightly closed container, protected from light.

Additional information. Even in the absence of light, Pyridoxine hydrochloride is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures.

Requirements

Definition. Pyridoxine hydrochloride contains not less than 98.5% and not more than 101.0% of $C_8H_{11}NO_3$,HCl, calculated with reference to the dried substance.

Identity tests

A. The absorption spectrum of a 10 μg/mL solution in hydrochloric acid (0.1 mol/l) VS, when observed between 230 nm and 350 nm, exhibits a maximum at about 290 nm; the absorbance of a 1-cm layer at this wavelength is about 0.43 (preferably use 2-cm cells for the measurement and calculate the absorbance of a 1-cm layer).

B. The absorption spectrum of a 0.5 mg/mL solution in phosphate buffer pH 6.9, TS, when observed between 230 nm and 350 nm, exhibits maxima at about 254 nm and 324 nm; the absorbances of a 1-cm layer at the maximum wavelengths are about 0.18 and 0.35, respectively (preferably use 2-cm cells for the measurement and calculate the absorbances of 1-cm layers).

C. In each of two test-tubes A and B, place 1 mL of a 0.1 mg/mL solution and 2 mL of sodium acetate (150 g/l) TS. To tube A add 1 mL of water and to tube B 1 mL of boric acid (50 g/l) TS and mix. Cool both tubes to about 20°C and rapidly add to each tube 1 mL of 2,6-dichloroquinone chlorimide/ethanol TS; a blue colour is produced in tube A, whereas in tube B no blue colour is observed.

D. A 0.05 g/mL solution yields reaction B described under 2.1 General identification tests as characteristic of chlorides.

Heavy metals. Use 0.5 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals. Procedure 3; determine the heavy metals content according to Method A; not more than 40 μg/g.

Clarity and colour of solution. A solution of 0.50 g in 10 mL of water is clear and colourless.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry to constant weight at ambient temperature under reduced pressure (not exceeding 0.6 kPa or about 5 mm of mercury) over silica gel, desiccant, R; it loses not more than 5.0 mg/g.

pH value. pH of a 10 mg/mL solution, 2.3-3.5.

Assay. In order to avoid overheating in the reaction medium, mix thoroughly throughout and stop the titration immediately after the end-point has been reached.

Dissolve 0.150 g in 5 mL of anhydrous formic acid R. Add 50 mL of acetic anhydride R. Carry out a potentiometric titration using

perchloric acid (0.1 mol/L) VS, as described under *2.6 Non-aqueous titration*.

1 mL of perchloric acid (0.1 mol/L) VS is equivalent to 20.56 mg of $C_8H_{11}NO_3$,HCl.