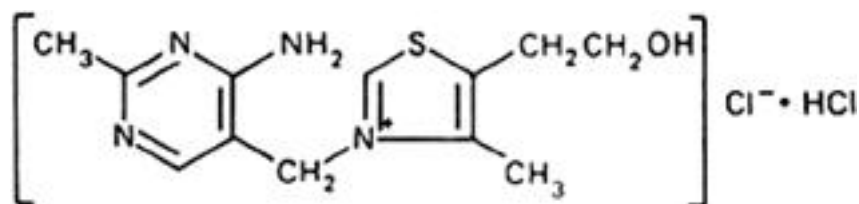


Thiamine hydrochloride (Thiamini hydrochloridum)

2018-01

Molecular formula. $C_{12}H_{17}ClN_4OS \cdot HCl$ **Relative molecular mass.** 337.3**Graphic formula.****Chemical name.** Thiamine chloride, hydrochloride; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium chloride, mono-hydrochloride; CAS Reg. No. 67-03-8.**Description.** Colourless crystals or a white or yellowish white, crystalline powder; odour, slight and characteristic.**Solubility.** Soluble in 1 part of water and in 100 parts of ethanol (~750 g/l) TS; practically insoluble in acetone R and ether R.**Category.** Component of vitamin B.**Storage.** Thiamine hydrochloride should be kept in a tightly closed, non-metallic container, protected from light.**Additional information.** Even in the absence of light, Thiamine hydrochloride is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures. When exposed to air, the anhydrous product rapidly absorbs about 4 g of water per 100 g. Melting temperature, about 248 °C with some decomposition. In solution at pH 4.0 or less, it loses its activity only very slowly. Neutral and alkaline solutions deteriorate rapidly, especially in contact with air.**Requirements****Definition.** Thiamine hydrochloride contains not less than 98.0% and not more than 101.0% of $C_{12}H_{17}ClN_4OS \cdot HCl$, calculated with reference to the dried substance.**Identity tests**

A. Dissolve 10 mg in 1 mL of water, add 1 mL of sodium hydroxide (~80 g/l) TS and 0.5 mL of potassium ferricyanide (10 g/l) TS; the solution remains pale yellow.

Shake with 5 mL of 2-butanol R and allow to stand for 5-10 minutes; in bright daylight or in ultraviolet light (365 nm) the 2-butanol layer shows a blue fluorescence.

B. Spread a small quantity of the powder on a watch-glass; the odour is slight and characteristic, resembling that of yeast.

C. A 0.05 g/mL solution yields reaction A described under [2.1 General identification tests](#) as characteristic of chlorides.

Heavy metals. Use 1.0 g for the preparation of the test solution as described under [2.2.3 Limit test for heavy metals](#), Procedure 1; determine the heavy metals content according to Method A; not more than 20 µg/g.**Clarity and colour of solution.** A solution of 2.0 g in 10 mL of water is clear and not more intensely coloured than standard colour solution Yw2 when compared as described under [1.11.1 Colour of liquids](#).**Sulfated ash.** Not more than 1.0 mg/g.**Loss on drying.** Dry to constant weight at 105°C; it loses not more than 50 mg/g.**pH value.** pH of a 25 mg/mL solution, 2.7-3.3.**Assay.** In order to avoid overheating in the reaction medium, mix thoroughly throughout the titration and stop the titration immediately after the end-point has been reached.

Dissolve 0.110 g in 5 mL of anhydrous formic acid R and add 50 mL of acetic anhydride R. Carry out a potentiometric titration using perchloric acid (0.1 M) VS, as described [2.6 Non-aqueous titration](#). Perform the titration within 2 minutes and carry out a blank titration.

1 mL of perchloric acid (0.1 M) VS is equivalent to 16.86 mg of $C_{12}H_{17}ClN_4OS \cdot HCl$.