Operating conditions—
Detector: An ultraviolet absorption photometer (wavelength: 254 nm).
Column: A stainless steel column about 4 mm in inside diameter and 15 to 30 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 to 10 μm in particle diameter).
Column temperature: A constant temperature of about 25°C.
Mobile phase: Dissolve 1.1 g of sodium 1-octanesulfonate in 1000 mL of diluted acetic acid (100) (1 in 100). To 600 mL of this solution add 400 mL of a mixture of methanol and acetonitrile (3:2).
Flow rate: Adjust the flow rate so that the retention time of thiamine is about 12 minutes.
Selection of column: Proceed with 10 μL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of thiamine and the internal standard in this order with the resolution between these peaks being not less than 6.
Containers and storage Containers—Hermetic containers.
Storage—Light-resistant.

Thiamine Hydrochloride Injection

Vitamin B₁ Hydrochloride Injection

塩酸チアミン注射液

Thiamine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 95% and not more than 115% of the labeled amount of thiamine hydrochloride (C₁₂H₁₇ClN₅O₇.HCl: 337.27).

Method of preparation Prepare as directed under Injections, with Thiamine Hydrochloride.

Description Thiamine Hydrochloride Injection is a clear, colorless liquid.

pH: 2.5 - 4.5

Identification To a volume of Thiamine Hydrochloride Injection, equivalent to 0.05 g of thiamine Hydrochloride according to the labeled amount, add water to make 25 mL. Proceed with 5 mL of this solution as directed in the Identification (1) under Thiamine Hydrochloride.

Assay Dilute with 0.001 mol/L hydrochloric acid TS if necessary, then measure exactly a volume of Thiamine Hydrochloride Injection, equivalent to about 0.02 g of thiamine hydrochloride (C₁₂H₁₇ClN₅O₇.HCl), and add 20 mL of methanol and 0.001 mol/L hydrochloric acid TS to make 100 mL. To 25 mL of this solution, exactly measured, add exactly 5 mL of the internal standard solution, add 0.001 mol/L hydrochloric acid TS to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of Thiamine Hydrochloride Reference Standard (determine previously its water content), and dissolve in 0.001 mol/L hydrochloric acid TS to make exactly 50 mL. To 10 mL of this solution, exactly measured, add 20 mL of methanol and 0.001 mol/L hydrochloric acid TS to make exactly 100 mL. To 25 mL of this solution, exactly measured, add exactly 5 mL of the internal standard solution, add water to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of Thiamine Hydrochloride Reference Standard (determine previously its water content), and dissolve in 0.01 mol/L hydrochloric acid TS to make exactly 50 mL. To 10 mL of this solution, exactly measured, add 20 mL of methanol and 0.001 mol/L hydrochloric acid TS to make exactly 100 mL. To 25 mL of this solution, exactly measured, add exactly 5 mL of the internal standard solution, add water to make 50 mL, and use this solution as the standard solution. Proceed as directed in the Assay under Thiamine Hydrochloride.

Amount (mg) of thiamine hydrochloride

\[
(C₁₂H₁₇ClN₅O₇.HCl) = \frac{Q_T \times 1}{Q_S \times \frac{5}{3}}
\]

Internal standard solution—A solution of methyl benzoate in methanol (1 in 200).

Containers and storage Containers—Hermetic containers.
Storage—Light-resistant.

Thiamine Hydrochloride Powder

Vitamin B₁ Hydrochloride Powder

塩酸チアミン散

Thiamine Hydrochloride Powder contains not less than 95% and not more than 115% of the labeled amount of thiamine hydrochloride (C₁₂H₁₇ClN₅O₇.HCl: 337.27).

Method of preparation Prepare as directed under Powders, with Thiamine Hydrochloride.

Identification To a portion of Thiamine Hydrochloride Powder, equivalent to 0.02 g of Thiamine Hydrochloride according to the labeled amount, add 50 mL of water and 10 mL of dilute acetic acid, shake, and filter. Proceed with 5 mL of the filtrate as directed in the Identification (1) under Thiamine Hydrochloride.

Purity Rancidity—Thiamine Hydrochloride Powder has no unpleasant or rancid odor. It is tasteless.

Assay Weigh accurately a quantity of Thiamine Hydrochloride Powder, equivalent to about 0.02 g of thiamine hydrochloride (C₁₂H₁₇ClN₅O₇.HCl), add 60 mL of 0.01 mol/L hydrochloric acid TS, and heat on a water bath for 30 minutes. Shake vigorously for 10 minutes, cool, add methanol to make exactly 100 mL, and centrifuge. Pipet 25 mL of the supernatant, add exactly 5 mL of the internal standard solution, add water to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of Thiamine Hydrochloride Reference Standard (determine previously its water content), and dissolve in 0.01 mol/L hydrochloric acid TS to make exactly 50 mL. To 10 mL of this solution, exactly measured, add 50 mL of 0.01 mol/L hydrochloric acid TS, and add methanol to make exactly 100 mL. To 25 mL of this solution, exactly measured, add exactly 5 mL of the internal standard solution, add water to make 50 mL, and use this solution as the standard solution. Proceed as directed in the Assay under Thiamine Hydrochloride.