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—Tight containers. Storage—Light-resistant.

Thiamine Hydrochloride Injection

Vitamin B_1 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 ($C_{12}H_{17}ClN_4OS.HCl$: 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 ($C_{12}H_{17}ClN_4OS.HCl$), 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 0.001 mol/L hydrochloric acid TS 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 ($C_{12}H_{17}ClN_4OS.HCl$)

= amount (mg) of Thiamine Hydrochloride Reference Standard, calculated on the anhydrous basis

$$\times \frac{Q_T}{Q_S} \times \frac{1}{5}$$

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 B_1 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 ($C_{12}H_{17}ClN_4OS.HCl$: 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 ($C_{12}H_{17}ClN_4OS.HCl$), 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.