

Thiamine Hydrochloride Oral Solution

Thiamine Hydrochloride Oral Solution contains not less than 95.0 percent and not more than 135.0 percent of the labeled amount of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS$ HCl).

Packaging and storage— Preserve in tight, light-resistant containers.

Identification— It meets the requirements for Identification test B under [Thiamine Hydrochloride Injection](#).

[Alcohol content, Method II 611](#) : between 90.0% and 110.0% of the labeled amount of C_2H_5OH , acetone being used as the internal standard.

Assay—

Mobile phase— Prepare a filtered and degassed mixture of 0.04 M aqueous monobasic potassium phosphate and methanol (55:45). Make adjustments if necessary.

Internal standard solution— Prepare a solution of methylparaben in Mobile phase having a concentration of about 100 μg per mL.

Standard preparation— Prepare a solution of [USP Thiamine Hydrochloride RS](#) in Mobile phase having an accurately known concentration of about 500 μg per mL. Pipet 10 mL of this solution and 10 mL of Internal standard solution into a 100-mL volumetric flask, dilute with Mobile phase to volume, and mix to obtain a Standard preparation having a known concentration of about 50 μg per mL.

Assay preparation— Quantitatively dilute an accurately measured volume of Oral Solution with Mobile phase to obtain a solution containing about 500 μg of thiamine hydrochloride per mL.

Pipet 10 mL of the resulting solution and 10 mL of Internal standard solution into a 100-mL volumetric flask, dilute with Mobile phase to volume, and mix.

Chromatographic system— The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm \times 30-cm column that contains packing L1. The flow rate is about 1.0 mL per minute.

Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative retention times are about 0.35 for thiamine and 1.0 for methylparaben; the resolution, R , between the thiamine and methylparaben peaks is not less than 6.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 25 μL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of thiamine hydrochloride ($\text{C}_{12}\text{H}_{17}\text{ClN}_4\text{OS}$ HCl) in each mL of the Oral Solution taken by the formula:

$$C(L/D)(R_U / R_S)$$

in which C is the concentration, in mg per mL, of [USP Thiamine Hydrochloride RS](#) in the Standard preparation; L is the labeled quantity, in mg per mL, of thiamine hydrochloride in the Oral Solution; D is the concentration, in mg per mL, of thiamine hydrochloride in the Assay preparation on the basis of the labeled quantity and the extent of dilution; and R_U and R_S are the ratios of the peak responses of thiamine to methylparaben obtained from the Assay preparation and the Standard preparation, respectively.