



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Thiamine Tablets

### [General Notices](#)

### Action and use

Vitamin B<sub>1</sub>.

### DEFINITION

Thiamine Tablets contain Thiamine Hydrochloride.

*The tablets comply with the requirements stated under Tablets and with the following requirements.*

### Content of thiamine hydrochloride, C<sub>12</sub>H<sub>17</sub>ClN<sub>4</sub>OS.HCl

92.5 to 107.5% of the stated amount.

### IDENTIFICATION

A. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions.

- (1) Shake a quantity of the powdered tablets containing 20 mg of Thiamine Hydrochloride with 20 mL of [water](#) and filter.
- (2) 0.1% w/v of [thiamine mononitrate BPCRS](#) in [water](#).

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [cellulose F<sub>254</sub>](#).
- (b) Use the mobile phase as described below.
- (c) Apply 2 µL of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, allow it to dry in air, heat at 105° for 30 minutes and spray with a mixture of equal volumes of a 0.3% w/v solution of [potassium hexacyanoferrate\(III\)](#) and a 10% w/v solution of [sodium hydroxide](#). Examine under [ultraviolet light](#) (365 nm).

#### MOBILE PHASE

15 volumes of [glacial acetic acid](#), 25 volumes of [water](#) and 60 volumes of [butan-1-ol](#).

#### CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).

B. Dissolve a quantity of the powdered tablets containing 20 mg of Thiamine Hydrochloride as completely as possible in 10 mL of [water](#) and 2 mL of 1M [acetic acid](#), filter, add 1.6 mL of 1M [sodium hydroxide](#), heat in a water bath for 30 minutes and cool. Add 5 mL of 5M [sodium hydroxide](#), 10 mL of [dilute potassium hexacyanoferrate\(III\) solution](#) and 10 mL of [butan-1-ol](#) and shake vigorously for 2 minutes. The alcohol layer shows an intense light blue fluorescence on exposure to ultraviolet light. Repeat the test but adding 0.9 mL of 1M [sodium hydroxide](#) and 0.2 g of [sodium sulfite](#) in place of the 1.6 mL of 1M sodium hydroxide; not more than a slight fluorescence is produced.

## ASSAY

Weigh and powder 20 tablets. Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

*For tablets containing less than 10 mg of Thiamine Hydrochloride:*

- (1) Add 5 mL of 0.1M [hydrochloric acid](#) and 50 mL of [water](#) to a quantity of the powdered tablets containing 6 mg of Thiamine Hydrochloride, shake for 20 minutes, dilute to 100 mL with [water](#) and filter.
- (2) 0.006% w/v of [thiamine mononitrate BPCRS](#) in 0.005M [hydrochloric acid](#).

*For tablets containing 10 mg or more of Thiamine Hydrochloride:*

- (1) Add 50 mL of 0.1M [hydrochloric acid](#) and 500 mL of [water](#) to a quantity of the powdered tablets containing 60 mg of Thiamine Hydrochloride, shake for 20 minutes, dilute to 1000 mL with [water](#) and filter.
- (2) 0.006% w/v of [thiamine mononitrate BPCRS](#) in 0.005M [hydrochloric acid](#).

### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (10 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography](#) (5 µm) (Nucleosil C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 2 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 244 nm.
- (f) Inject 20 µL of each solution.

### MOBILE PHASE

Dissolve 1 g of sodium [heptane sulfonate](#) in a mixture of 180 mL of [methanol](#) and 10 mL of [triethylamine](#), diluting to 1000 mL with [water](#) and adjusting the pH to 3.2 with [orthophosphoric acid](#).

### DETERMINATION OF CONTENT

Calculate the content of  $C_{12}H_{17}ClN_4OS \cdot HCl$  using the declared content of  $C_{12}H_{17}N_5O_4S$  in [thiamine mononitrate BPCRS](#). Each mg of  $C_{12}H_{17}N_5O_4S$  is equivalent to 1.030 mg of  $C_{12}H_{17}ClN_4OS \cdot HCl$ .

## STORAGE

Thiamine Tablets should be kept free from contact with metal and protected from light.

When vitamin B<sub>1</sub> tablets are prescribed or demanded, Thiamine Tablets shall be dispensed or supplied.