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

Thiamine Injection

General Notices

Action and use

Vitamin B_1.

DEFINITION

Thiamine Injection is a sterile solution of Thiamine Hydrochloride in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of thiamine hydrochloride, $C_{12}H_{17}ClN_4OS,HCl$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless or almost colourless solution.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Use the injection, diluted with *water*, if necessary, to contain 0.1% w/v of Thiamine Hydrochloride.
(2) 0.1% w/v of *thiamine mononitrate BPCRS* in *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *cellulose F_{254}*.
(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, 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* and 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. To a volume containing 20 mg of Thiamine Hydrochloride diluted, if necessary, to 10 mL with *water*, add 2 mL of 1M *acetic acid* and 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 hexacyano-ferrate(III) solution* and 10 mL of *butan-1-ol* and shake vigorously for 2 minutes. The upper 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.

C. To a mixture of 0.1 mL of *nitrobenzene* and 0.2 mL of *sulfuric acid* add a volume of the injection containing 5 mg of Thiamine Hydrochloride. Allow to stand for 10 minutes, cool in ice and add slowly with stirring 5 mL of *water* followed by 5 mL of 10M *sodium hydroxide*. Add 5 mL of *acetone* and allow to stand. No violet colour is produced in the upper layer.

TESTS

Acidity

pH, 2.8 to 3.4, Appendix V L.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute a volume of the injection containing 0.1 g of Thiamine Hydrochloride to 100 mL with 0.1M *hydrochloric acid* and further dilute 5 mL to 100 mL with *water*.
(2) 0.005% 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 $C_{12}H_{17}ClN_4OS,HCl$ 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 $C_{12}H_{17}ClN_4OS,HCl$.

STORAGE

Thiamine Injection should be protected from light.

When vitamin B_1 injection is prescribed or demanded, Thiamine Injection shall be dispensed or supplied.