Quality standards

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

Metaraminol Tartrate

General Notices

 $C_9H_{13}NO_2, C_4H_6O_6$ 317.3 17171-57-2

Action and use

Adrenoceptor agonist.

Preparation

Metaraminol Injection

DEFINITION

Metaraminol Tartrate is (1R,2S)-2-amino-1-(3-hydroxyphenyl)propan-1-ol hydrogen (2R,3R)-tartrate. It contains not less than 99.0% and not more than 101.0% of $C_9H_{13}NO_2$, $C_4H_6O_6$, calculated with reference to the dried substance.

CHARACTERISTICS

A white, crystalline powder.

Freely soluble in water; sparingly soluble in ethanol (96%); practically insoluble in ether.

IDENTIFICATION

- A. In the test for Related substances the principal spot in the chromatogram obtained with solution (2) corresponds to that in the chromatogram obtained with solution (4).
- B. To 0.5 mL of a 0.05% w/v solution add 0.5 mL of *phosphomolybdotungstic reagent* and 5 mL of *dilute* sodium carbonate solution and allow to stand for 5 minutes. An intense blue colour is produced.
- C. To 4 mL of a 0.05% w/v solution add 5 mL of <u>borate buffer pH 9.6</u> and 1 mL of a freshly prepared 0.5% w/v solution of <u>sodium 1,2-naphthaquinone-4-sulfonate</u> and allow to stand for 1 minute. Add 0.2 mL of a 2%

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v/v solution of <u>benzalkonium chloride solution</u> and 5 mL of <u>toluene</u> and shake. A mauve colour is immediately produced in the toluene layer (distinction from phenylephrine).

TESTS

Acidity

pH of a 5% w/v solution, 3.2 to 3.5, Appendix V L.

Phenones

<u>Absorbance</u> of a 0.2% w/v solution at 310 nm, not more than 0.2, calculated with reference to the dried substance, <u>Appendix II B</u>.

Related substances

Carry out in subdued light the method for <u>thin-layer chromatography</u>, <u>Appendix III A</u>, using the following solutions in <u>methanol</u>.

- (1) 1.0% w/v of the substance being examined.
- (2) 0.050% w/v of the substance being examined.
- (3) 0.0050% w/v of the substance being examined.
- (4) 0.050% w/v of metaraminol tartrate BPCRS.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a silica gel precoated plate (Merck silica gel 60 plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 10 µL of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry in air and spray with a solution prepared in the following manner. Mix 25 mL of a 0.45% w/v solution of <u>sulfanilic acid</u> in 1M <u>hydrochloric acid</u> with 1.5 mL of a 5% w/v solution of <u>sodium nitrite</u>, allow to stand for 5 minutes and mix cautiously with 25 mL of 2M <u>sodium carbonate</u>.

MOBILE PHASE

10 volumes of 13.5м <u>ammonia</u>, 80 volumes of <u>chloroform</u> and 80 volumes of <u>methanol</u>.

LIMITS

Any <u>secondary spot</u> in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (3) (0.5%).

Loss on drying

When dried to constant weight at 105°, loses not more than 0.5% of its weight. Use 1 g.

Sulfated ash

Not more than 0.1%, Appendix IX A.

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ASSAY

Carry out Method I for <u>non-aqueous titration</u>, <u>Appendix VIII A</u>, using 0.6 g and <u>crystal violet solution</u> as indicator. Each mL of 0.1 M perchloric acid VS is equivalent to 31.73 mg of $C_9H_{13}NO_2, C_4H_6O_6$.