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

Metaraminol Injection

General Notices

Action and use

Adrenoceptor agonist.

DEFINITION

Metaraminol Injection is a sterile solution of Metaraminol Tartrate in Water for Injections.

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

Content of metaraminol, $C_9H_{13}NO_2$

90.0 to 110.0% of the stated amount.

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 (5).
B. Dilute a volume containing the equivalent of 5 mg of metaraminol to 10 mL with *water* and extract with four 15 mL quantities of *chloroform*. To 0.5 mL of the aqueous layer 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 the aqueous layer obtained in test B add 5 mL of *borate buffer pH 9.6* and 1 mL of a freshly prepared 0.5% w/v solution of *sodium 1,2-naphthoquinone-4-sulfonate* and allow to stand for 1 minute. Add 0.2 mL of a 2% v/v solution of *benzalkonium chloride solution* and 5 mL of *toluene* and shake. A mauve colour is produced immediately in the toluene layer (distinction from phenylephrine).

TESTS

Acidity

pH, 3.2 to 4.5, Appendix V L.

Related substances

Carry out in subdued light the method for *thin-layer chromatography*, Appendix III A, using a silica gel precoated plate (Merck silica gel 60 plates are suitable) and a mixture of 10 volumes of 13.5M *ammonia*, 80 volumes of *chloroform* and 80 volumes of *methanol* as the mobile phase. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) evaporate a volume of the injection containing the equivalent of 20 mg of metaraminol to dryness, dissolve the residue as completely as possible in 2 mL of *methanol* and filter. For solution (2) dilute 1 volume of solution (1) to 20 volumes with *methanol*. For solution (3) dilute 1 volume of solution (1) to 100 volumes with *methanol*. Solution (4) contains 0.1% w/v of *methyl 4-hydroxybenzoate* in *methanol*. Solution (5) contains 0.050% w/v of *metaraminol tartrate BPCRS* in *methanol*. After removal of the plate, allow it to dry in air and spray with a solution prepared in the following manner. Mix

25 mL of a 0.45% w/v solution of *sulfanilic acid* in 1M *hydrochloric acid* with 1.5 mL of a 5% w/v solution of *sodium nitrite*, allow to stand for 5 minutes and mix cautiously with 25 mL of 2M *sodium carbonate*. Any *secondary spot* in the chromatogram obtained with solution (1), other than any spot corresponding to methyl 4-hydroxybenzoate, is not more intense than the spot in the chromatogram obtained with solution (3) (1%).

ASSAY

To a quantity containing the equivalent of 10 mg of metaraminol add sufficient *water* to produce 200 mL. Wash 25 mL with four 25 mL quantities of *chloroform*, discard the washings and filter the aqueous solution. Measure the *absorbance* of the filtrate at the maximum at 272 nm, Appendix II B. Calculate the content of $C_9H_{13}NO_2$ taking 111 as the value of A(1%, 1 cm) at the maximum at 272 nm.

STORAGE

Metaraminol Injection should be protected from light.

LABELLING

The strength is stated in terms of the equivalent amount of metaraminol in a suitable dose-volume.