Ephedrine sulfate injection (Ephedrini sulfatis injectio)

2015-01

Description. A clear, colourless solution.

Category. Anti-asthmatic drug.

Storage. Ephedrine sulfate injection should be protected from light.

Requirements

Complies with the monograph for *Parenteral preparations*.

Definition. Ephedrine sulfate injection is a sterile solution of ephedrine sulfate in water for injections. The solution is sterilized by a suitable method (see *5.8 Methods of sterilization*).

Ephedrine sulfate injection contains not less than 95.0% and not more than 105.0% of the amount of $(C_{10}H_{15}NO)_2,H_2SO_4$ stated on the label.

Identity tests

-Either tests A and D or tests B, C and D may be applied.

To a volume of the injection equivalent to 0.1 g of Ephedrine sulfate add 5 mL of ethanol (~750 g/L) TS and evaporate to dryness on a water-bath with the aid of a stream of air. Use the residue for tests A and C.

A. Carry out the examination with the residue as described under *1.7 Spectrophotometry in the infrared region*. The infrared absorption spectrum is concordant with the spectrum obtained from ephedrine sulfate RS similarly treated or with the *reference spectrum* of ephedrine sulfate.

B. Measure the optical rotation of the injection; it is levorotatory.

C. Dissolve 10 mg of the residue in 1 mL of water and add 0.1 mL of copper(II) sulfate (80 g/L) TS, followed by 2 mL of sodium hydroxide (~80 g/L) TS; a violet colour is produced. To this solution add 2 mL of 1-butanol R and shake; a reddish violet colour is produced in the butanol layer.

D. The injection yields reaction A described under *2.1 General identification tests* as characteristic of sulfates.

pH value. pH of the injection, 4.5–7.0.

Related substances

Carry out the test as described under *1.14.1 Thin-layer chromatography* using silica gel R1 as the coating substance and a mixture of 80 volumes of 2-propanol R, 15 volumes of ammonia (~260 g/L) TS and 5 volumes of chloroform R as the mobile phase. Apply separately to the plate 10 µL of each of the following two solutions. For solution (A) dilute a volume of the injection equivalent to 0.1 g of Ephedrine sulfate to 5 mL with methanol R and for solution (B) dilute 0.5 mL of solution A to 100 mL with methanol R. After removing the plate from the chromatographic chamber allow it to dry in air, spray with a mixture of 0.2 g of triketohydrindene hydrate R dissolved in 95 mL of 1-butanol R and 5 mL of acetic acid (~120 g/L) TS and heat to 110 °C for 5 minutes. Examine the chromatogram in daylight.

Any secondary spot obtained with solution A is not more intense than that obtained with solution B. Disregard any spot of lighter colour than the background.

Assay

Transfer an accurately measured volume of the injection equivalent to about 0.25 g of Ephedrine sulfate to a separator, dilute if necessary with water to a volume of about 10 mL, add 3 g of sodium chloride R to saturate the solution, then add 5 mL of sodium hydroxide (1 mol/L) VS and extract four times, each with 25 mL of chloroform R. Wash the combined chloroform extracts with 10 mL of a saturated solution of sodium chloride R and filter through purified cotton saturated with chloroform R. Shake the aqueous wash solution with 10 mL of chloroform R and add it to the main chloroform extract. Add 0.25 mL of methyl red/ethanol TS and titrate with perchloric acid/dioxan (0.1 mol/L) VS, as described under *2.6 Non-aqueous titration*, Method A.

Each mL of perchloric acid/dioxan (0.1 mol/L) VS is equivalent to 21.43 mg of $(C_{10}H_{15}NO)_2,H_2SO_4$.

Bacterial endotoxins. Carry out the test as described under *3.4 Test for bacterial endotoxins*; contains less than 1.7 IU of endotoxin per mg Ephedrine sulfate.