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

Ephedrine Hydrochloride Tablets

General Notices

Action and use

Adrenoceptor agonist.

DEFINITION

Ephedrine Hydrochloride Tablets contain Ephedrine Hydrochloride.

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

Content of ephedrine hydrochloride, $C_{10}H_{15}NO,HCl$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the tablets containing 0.1 g of Ephedrine Hydrochloride with 20 mL of 0.1M *hydrochloric acid*, filter, wash the filtrate with two 20 mL quantities of *chloroform* and discard the chloroform. Make the aqueous layer alkaline with 5M *ammonia* and extract with two 30 mL quantities of a mixture of 3 volumes of *chloroform* and 1 volume of *ethanol (96%)*. Dry the combined extracts over *anhydrous sodium sulfate*, filter and evaporate to a low volume at a pressure of 2 kPa. Prepare a disc using 0.3 g of *potassium bromide*, apply the chloroform solution to the surface of the disc and heat at 50° for 2 minutes. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of ephedrine *(RS 121)*.
B. 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 (3).
C. Triturate a quantity of the powdered tablets containing 0.4 g of Ephedrine Hydrochloride with two 10 mL quantities of *chloroform* and discard the chloroform. Macerate the residue with 30 mL of warm *ethanol (96%)* for 20 minutes, filter, evaporate the filtrate to dryness on a water bath and dry the residue at 80°. Dissolve 10 mg of the residue in 1 mL of *water* and add 0.1 mL of *weak copper sulfate solution* followed by 1 mL of 5M *sodium hydroxide*; a violet colour is produced. Add 1 mL of *ether* and shake; the ether layer is purple and the aqueous layer is blue.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Extract a quantity of the powdered tablets containing 0.10 g of Ephedrine Hydrochloride with 5 mL of *methanol*, filter and use the filtrate.
(2) Dilute 1 volume of solution (1) to 10 volumes with *methanol*.
(3) 0.20% w/v of *ephedrine hydrochloride BPCRS* in *methanol*.
(4) Dilute 1 volume of solution (1) to 200 volumes with *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel G*.
(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, allow it to dry in air, spray with *ninhydrin solution* and heat at 110° for 5 minutes.

MOBILE PHASE

5 volumes of *chloroform*, 15 volumes of 13.5M *ammonia* and 80 volumes of *propan-2-ol*.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (4). Disregard any spot of lighter colour than the background.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 50 mg of Ephedrine Hydrochloride with 30 mL of *methanol* for 10 minutes, add sufficient *water* to produce 50 mL, filter through glass-fibre paper (Whatman GF/C is suitable) and use the filtrate.
(2) 0.1% w/v of *ephedrine hydrochloride BPCRS* in methanol (60%).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (10 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 263 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

0.005M *dioctyl sodium sulfosuccinate* in a mixture of 1 volume of *glacial acetic acid*, 35 volumes of *water* and 65 volumes of *methanol*.

DETERMINATION OF CONTENT

Calculate the content of $C_{10}H_{15}NO,HCl$ using the declared content of $C_{10}H_{15}NO,HCl$ in *ephedrine hydrochloride BPCRS*.