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

Ephedrine Nasal Drops

General Notices

Action and use

Adrenoceptor agonist.

DEFINITION

Ephedrine Nasal Drops are a solution of Ephedrine Hydrochloride in a suitable aqueous vehicle.

The nasal drops comply with the requirements stated under Nasal Preparations and with the following requirements.

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

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. To a quantity of the nasal drops containing 0.1 g of Ephedrine Hydrochloride add 2 mL of *2M hydrochloric acid*, shake with two 20 mL quantities of *chloroform* and discard the chloroform. Add 5M *ammonia* until the aqueous layer is alkaline, extract with two 30 mL quantities of a mixture of 3 volumes of *chloroform* and 1 volume of *ethanol*, dry the combined extracts over *anhydrous sodium sulfate*, filter and evaporate to dryness at a pressure of 2 kPa, heating gently to remove the last traces of solvent. The *infrared absorption spectrum* of the residue, 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 (4).

TESTS

Acidity or alkalinity

pH, 4.0 to 7.0, Appendix V L.

Related substances

Carry out 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 80 volumes of *propan-2-ol*, 15 volumes of 13.5M *ammonia* and 5 volumes of *chloroform* as the mobile phase. Apply separately to the plate 20 µL of each of the following solutions. For solution (1) use the nasal drops diluted, if necessary, with *water* to contain 0.5% w/v of Ephedrine Hydrochloride. For solution (2) dilute 1 volume of solution (1) to 5 volumes with *methanol*. For solution (3) dilute 1 volume of solution (1) to 200 volumes with *water*. Solution (4) contains 0.1% w/v of *ephedrine hydrochloride BPCRS* in *methanol*. After removal of the plate, allow it to dry in air, spray with *ninhydrin solution* and heat at 100° for 5 minutes. Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (3). Disregard any spot of lighter colour than the background and any spot remaining on the line of application.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Solution (1) is a 0.1% w/v solution of *ephedrine hydrochloride BPCRS* in *methanol (65%)*. For solution (2) dilute the nasal drops with *methanol (80%)* to contain 0.1% w/v of Ephedrine Hydrochloride.

The chromatographic procedure may be carried out using (a) 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) 0.005M *dioctyl sodium sulfosuccinate* in a mixture of 65 volumes of *methanol*, 35 volumes of *water* and 1 volume of *glacial acetic acid* as the mobile phase with a flow rate of 2 mL per minute and (c) a detection wavelength of 263 nm.

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

When ephedrine nasal drops are prescribed or demanded no strength being stated, nasal drops containing 0.5% w/v of ephedrine hydrochloride shall be dispensed or supplied.