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

Papaverine Injection

General Notices

Action and use

Phosphodiesterase inhibitor; smooth muscle relaxant.

DEFINITION

Papaverine Injection is a sterile solution of Papaverine Hydrochloride in Water for Injections.

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

Content of papaverine hydrochloride, $C_{20}H_{21}NO_4$, HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. To a volume of the injection containing 60 mg of Papaverine Hydrochloride add 2 mL of *ethanol (96%)*, evaporate to dryness on a steam bath with the aid of a stream of *nitrogen* and dry the residue at 105° for 2 hours. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of papaverine hydrochloride *(RS 415)*.
B. Yields reaction A characteristic of *chlorides*, Appendix VI.

TESTS

Acidity

pH, 2.0 to 4.0, Appendix V L.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. For solution (1) dilute a volume of the injection, if necessary, with *methanol (50%)* to produce a solution containing 0.06% w/v of Papaverine Hydrochloride. For solution (2) dilute 1 volume of solution (1) to 100 volumes with *methanol* (50%).Solution (3) contains 0.0005% w/v of *papaverine hydrochloride BPCRS* and 0.005% w/v of *noscapine* in the mobile phase.

The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 4.6 mm) packed with *endcapped octadecylsilyl silica gel for chromatography* (5 µm) (Phenomenex Luna C(18)2 is suitable), (b) as the mobile phase with a flow rate of 1 mL per minute a mixture prepared by adding 700 mL of *methanol* containing 2.22 g of *dioctyl sodium sulfosuccinate* to 100 mL of *water* containing 1.36 g of *sodium acetate*, diluting to 1 litre with *water* and adjusting the pH to 5.5 with *glacial acetic acid* and (c) a detection wavelength of 250 nm.

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peaks due to papaverine hydrochloride and noscapine is at least 3.0.

In the chromatogram obtained with solution (1), the sum of the areas of any *secondary peaks* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Solution (1) contains 0.0045% w/v of *papaverine hydrochloride BPCRS* in *methanol (50%)*. For solution (2) dilute a volume of the injection, if necessary, with *methanol* (50%) to produce a solution containing 0.0045% w/v of Papaverine Hydrochloride.

The chromatographic method described under Related substances may be used.

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peaks due to papaverine hydrochloride and noscapine is at least 3.0.

Calculate the content of $C_{20}H_{21}NO_4$,HCl in the injection using the declared content of $C_{20}H_{21}NO_4$,HCl in *papaverine hydrochloride BPCRS*.

STORAGE

Papaverine Injection should be protected from light.