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

Pentazocine Injection

General Notices

Action and use

Opioid receptor agonist; analgesic.

DEFINITION

Pentazocine Injection is a sterile solution in Water for Injections of either Pentazocine Lactate or pentazocine lactate prepared by the interaction of Pentazocine and Lactic Acid.

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

Content of pentazocine, $C_{19}H_{27}NO$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless or almost colourless solution.

IDENTIFICATION

A. To a volume containing the equivalent of 90 mg of pentazocine add 5 mL of 0.1M *sodium hydroxide* and shake the resulting solution with 5 mL of *chloroform*. Wash the chloroform extract with 2 mL of *water*, dry over *anhydrous sodium sulfate* and filter. Evaporate the chloroform using a rotary evaporator and dry the oily residue at a temperature not exceeding 25° at a pressure of 2 kPa for 1 hour. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of pentazocine (form B) (*RS 261*).

B. Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 10 volumes of 18M *ammonia*, 10 volumes of *ethyl acetate*, 30 volumes of *water* and 50 volumes of *absolute ethanol* as the mobile phase but allowing the solvent front to ascend 10 cm above the line of application. Apply separately to the plate 5 µL of each of the following solutions. For solution (1) dilute a quantity of the injection with sufficient *methanol* to produce a solution containing the equivalent of 0.75% w/v of pentazocine. Solution (2) contains 0.4% w/v of *calcium lactate* in *methanol*. After removal of the plate, allow it to dry in air, spray with a 1% w/v solution of *potassium permanganate* and examine in daylight. The principal spot in the chromatogram obtained with solution (1) is similar in colour, position and size to that in the chromatogram obtained with solution (2).

TESTS

Acidity

pH, 4.0 to 5.0, Appendix V L.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 3 volumes of *methanol*, 3 volumes of *isopropylamine* and 94 volumes of *chloroform* as the mobile phase. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) dilute a quantity of the injection with sufficient *ethanol* (*96%*) to produce a solution containing the equivalent of 2.0% w/v of pentazocine. For solution (2) dilute 1 volume of solution (1) to 100 volumes with *ethanol* (*96%*). For solution (3) dilute 1 volume of solution (1) to 200 volumes with *ethanol* (*96%*). For solution (4) dilute 1 volume of solution (1) to 400 volumes with *ethanol* (*96%*). After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*. Heat the plate at 105° for 15 minutes, allow to cool, expose to iodine vapour and re-examine under *ultraviolet light (254 nm)*. By each method of visualisation any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%), not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.5%) and not more than four such spots are more intense than the spot in the chromatogram obtained with solution (4) (0.25%). Disregard any spot remaining on the line of application.

ASSAY

To a quantity containing the equivalent of 0.15 g of pentazocine add sufficient *water* to produce 100 mL. To 5 mL add 1 mL of 1M *hydrochloric acid*, dilute to 100 mL with *water* and measure the *absorbance* of the resulting solution at the maximum at 278.5 nm, Appendix II B. Calculate the content of $C_{19}H_{27}NO$ taking 69.0 as the value of A(1%, 1 cm) at the maximum at 278.5 nm.

STORAGE

Pentazocine Injection should be protected from light.

LABELLING

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