



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

Meptazinol Injection

[General Notices](#)

Action and use

Opioid receptor partial agonist; analgesic.

DEFINITION

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

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

Content of meptazinol, $C_{15}H_{23}NO$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. The [light absorption](#), [Appendix II B](#), in the range 220 to 330 nm of the solution obtained in the Assay exhibits a maximum at 273 nm.
- B. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions in [ethanol \(96%\)](#).
- (1) Dilute the injection, if necessary, to contain the equivalent of 0.05% w/v of meptazinol.
- (2) 0.05% w/v of [meptazinol hydrochloride BPCRS](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel \$F_{254}\$](#) (Merck [silica gel 60 \$F_{254}\$](#) plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 10 μ L of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#).

MOBILE PHASE

1 volume of 18M [ammonia](#), 20 volumes of [absolute ethanol](#) and 79 volumes of [toluene](#).

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in intensity, position and size to that in the chromatogram obtained with solution (2).

TESTS

Acidity

Colour of solution

The injection is not more intensely coloured than [reference solution Y₅](#), [Appendix IV B](#), Method II.

Related substances

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions in [water](#).

- (1) Dilute a volume of the injection, if necessary, to produce a solution containing the equivalent of 1.0% w/v of meptazinol.
- (2) Dilute 1 volume of solution (1) to 100 volumes.
- (3) Dilute 1 volume of solution (2) to 2 volumes.

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel](#) (Merck [silica gel 60 F₂₅₄](#) plates are suitable).
- (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, dry in air, examine under [ultraviolet light \(254 nm\)](#), expose to iodine vapour for 2 hours and examine again.

MOBILE PHASE

1 volume of 18M [ammonia](#), 30 volumes of [chloroform](#) and 70 volumes of [ethyl acetate](#).

LIMITS

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%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.5%).

ASSAY

Dilute a suitable volume of the injection with sufficient [water](#) to produce a solution containing the equivalent of 0.01% w/v of meptazinol and measure the [absorbance](#) at the maximum at 273 nm, [Appendix II B](#). Calculate the content of C₁₅H₂₃NO from the [absorbance](#) obtained using a 0.01% w/v solution of [meptazinol hydrochloride BPCRS](#) and from the declared content of C₁₅H₂₃NO in [meptazinol hydrochloride BPCRS](#).

LABELLING

The label of the sealed container states the quantity of Meptazinol Hydrochloride contained in it in terms of the equivalent amount of meptazinol.