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

# Zuclopenthixol Decanoate Injection

General Notices

**Action and use**

Dopamine receptor antagonist; neuroleptic.

## DEFINITION

Zuclopenthixol Decanoate Injection is a sterile solution of Zuclopenthixol Decanoate in a suitable vegetable oil.

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

**Content of zuclopenthixol decanoate, $C_{32}H_{43}ClN_2O_2S$**

95.0 to 105.0% of the stated amount.

## IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions, protected from light.
(1) Dilute a volume of the injection with *ethanol (96%)* to contain 0.5% w/v of Zuclopenthixol Decanoate.
(2) 0.5% w/v of *zuclopenthixol decanoate dihydrochloride BPCRS* in *ethanol (96%)*.
(3) 0.5% w/v each of *zuclopenthixol decanoate dihydrochloride BPCRS* and *zuclopenthixol acetate dihydrochloride BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel $F_{254}$* (Merck silica gel 60 $F_{254}$ plates are suitable). Before use, heat the plate at 110° for 30 minutes.
(b) Use the mobile phase as described below.
(c) Apply 5 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 a 1% w/v solution of *sodium molybdate* in *sulfuric acid*, heat at 110° for 20 minutes and examine in daylight.

MOBILE PHASE

3 volumes of *diethylamine* and 90 volumes of *cyclohexane* as the mobile phase, using an unlined tank.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows two clearly separated spots.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to zuclopenthixol decanoate in the chromatogram obtained with solution (2).

## TESTS

**Related substances**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in *acetonitrile*, protected from light.

(1) Dilute the injection to contain 0.50% w/v of Zuclopenthixol Decanoate.
(2) 0.015% w/v of *zuclopenthixol hydrochloride BPCRS*.
(3) 0.0025% w/v of *2-chlorothioxanthone BPCRS*.
(4) 0.005% w/v of trans-*clopenthixol decanoate dihydrochloride BPCRS*.
(5) 0.015% w/v of *zuclopenthixol hydrochloride BPCRS*, 0.0025% w/v of *2-chlorothioxanthone BPCRS* and 0.005% w/v of trans-*clopenthixol decanoate dihydrochloride BPCRS* in solution (1).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Waters Symmetry C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use a column temperature of 40°.
(e) Use a detection wavelength of 270 nm.
(f) Inject 20 µL of each solution.
(g) For solution (1), allow the chromatography to proceed for twice retention time of the principal peak.

MOBILE PHASE

0.1 volume of *orthophosphoric acid*, 26 volumes of 0.02M *dioctyl sodium sulfosuccinate* (prepared by dissolving 8.89 g of *dioctyl sodium sulfosuccinate* in 500 mL of *water*, stirring for 6 to 8 hours and diluting to 1000 mL with *water*) and 74 volumes of *ethanol (96%)*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (5) shows clearly separated peaks.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to zuclopenthixol is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (3%);

the area of any peak corresponding to 2-chlorothioxanthone is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.5%);

the area of any peak corresponding to *trans*-clopenthixol decanoate is not greater than the area of the principal peak in the chromatogram obtained with solution (4) (1%).

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions solutions in *acetonitrile* protected from light.

(1) Dilute a volume of the injection to contain 0.50% w/v of Zuclopenthixol Decanoate.
(2) 0.57% w/v of *zuclopenthixol decanoate dihydrochloride BPCRS*.
(3) 0.015% w/v of *zuclopenthixol hydrochloride BPCRS*, 0.0025% w/v of *2-chlorothioxanthone BPCRS* and 0.005% w/v of trans-*clopenthixol decanoate dihydrochloride BPCRS* in solution (1).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows clearly separated peaks.

DETERMINATION OF CONTENT

Calculate the content of $C_{32}H_{43}ClN_3O_2S$ using the declared content of $C_{32}H_{43}ClN_3O_2S$ in *zuclopenthixol decanoate dihydrochloride BPCRS*. Each mg of zuclopenthixol decanoate dihydrochloride is equivalent to 0.8852 mg of zuclopenthixol decanoate.

## STORAGE

Zuclopenthixol Decanoate Injection should be protected from light.