



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

## Desmopressin Injection

[General Notices](#)

### Action and use

Vasopressin analogue; treatment of diabetes insipidus; nocturnal enuresis; haemophilia; von Willebrand's disease.

### DEFINITION

Desmopressin Injection is a sterile solution of Desmopressin in Water for Injections.

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

**Content of desmopressin,  $C_{46}H_{64}N_{14}O_{12}S_2$**

90.0 to 110.0% of the stated amount of the peptide.

### CHARACTERISTICS

A colourless solution.

### IDENTIFICATION

In the Assay, the principal peak in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

### TESTS

#### Acidity

pH, 3.5 to 6.0, [Appendix V L](#).

#### Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions and the *normalisation procedure*.

- (1) Dilute the injection, if necessary, with [water](#) to produce a solution containing 0.0004% w/v of the peptide.
- (2) Dissolve the contents of a vial of [desmopressin impurity standard BPCRS](#) in 2 mL of [water](#).

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (12 cm x 4.0 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm).
- (b) Use gradient elution and the mobile phase described below.

- (c) Use a flow rate of 1.5 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 220 nm.
- (f) Inject 200 µL of each solution.

#### MOBILE PHASE

Mobile phase A 0.067M mixed [phosphate buffer solution pH 7.0](#).

Mobile phase B A mixture of [acetonitrile for chromatography](#) and mobile phase A in equal volumes.

Time (Minutes)	Mobile phase A%	Mobile phase B%	Comment
0-4	76	24	isocratic
4-18	76→58	24→42	linear gradient
18-35	58→48	42→52	linear gradient
35-40	48→76	52→24	linear gradient
40-50	76	24	re-equilibration

The retention time of [4- L -glutamic acid]desmopressin is about 14 minutes and the retention time of desmopressin is about 15 minutes.

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the [resolution](#) between the two principal peaks is at least 3.4.

#### LIMITS

In the chromatogram obtained with solution (1):

the area of any [secondary peak](#) is not more than 4.0%;

the total area of any such peaks is not more than 5.0%.

Disregard any peak due to the solvent or with an area less than 2.0%.

#### [Bacterial endotoxins](#)

Carry out the [test for bacterial endotoxins, Appendix XIV C](#). The endotoxin limit concentration is less than 10 IU per µg peptide.

## ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) Dilute a volume of the injection in [water](#) to give a final concentration of 0.0004 % w/v of the peptide.
- (2) 0.0004% w/v of [desmopressin BPCRS](#) in [water](#).
- (3) Dissolve the contents of a vial of [desmopressin impurity standard BPCRS](#) in 2 mL of [water](#).

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (12 cm x 4.0 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Nucleosil C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 2 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 220 nm.
- (f) Inject 200 µL of each solution.

#### MOBILE PHASE

20 volumes of [acetonitrile for chromatography](#) and 80 volumes of 0.067 M mixed phosphate buffer solution, pH 7.0.

The retention time of desmopressin is about 5 minutes; if necessary adjust the concentration of [acetonitrile](#) in the mobile phase to obtain a retention time of about 5 minutes.

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the two principal peaks at least 2.8.

#### DETERMINATION OF CONTENT

Calculate the content of  $C_{46}H_{64}N_{14}O_{12}S_2$  in the injection from the chromatograms obtained and from the declared content of  $C_{46}H_{64}N_{14}O_{12}S_2$  in [desmopressin BPCRS](#).

## STORAGE

Desmopressin Injection should be protected from light and stored at a temperature of 2° to 8°.