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

# Desmopressin Nasal Spray

General Notices

**Action and use**

Vasopressin analogue; treatment of diabetes insipidus.

## DEFINITION

Desmopressin Nasal Spray is a solution of Desmopressin containing suitable buffering agents and preservatives in a suitable container.

*The nasal spray complies with the requirements stated under Nasal 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 5.5, Appendix V L.

**Related substances**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions and the *normalisation procedure*.

(1) If necessary dilute a volume of the nasal spray in a solution of 0.9% w/v of *sodium chloride* to produce a solution containing 0.01 to 0.015 % w/v of the peptide.
(2) Dissolve the contents of a vial of *desmopressin impurity standard BPCRS* in 1 mL of a solution of 0.9% w/v *sodium chloride*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (12 cm × 4.0 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Nucleosil C18 is suitable).
(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 100 µL of each solution.

MOBILE PHASE

*Mobile phase A* *0.067M mixed phosphate buffer solution, pH 7.0*.

*Mobile phase B* *acetonitrile for chromatography*

| Time (Minutes) | Mobile phase A (% v/v) | Mobile phase B (% v/v) | Comment |
|---|---|---|---|
| 0-16 | 83 | 17 | isocratic |
| 16-38 | 83→72 | 17→28 | linear gradient |
| 38-46 | 72 | 28 | isocratic |
| 46-50 | 72→83 | 28→17 | linear gradient |
| 50-60 | 83 | 17 | re-equilibration |

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 2.0;

the peak due to desmopressin is clearly separated from any peaks due to the excipients stated on the label.

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, any antimicrobial preservative stated on the label and any peak with an area less than 0.3%.

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) If necessary dilute a volume of the nasal spray in a solution of 0.9% w/v of *sodium chloride* to give a final concentration in the range of 0.01 to 0.015 % w/v of the peptide.
(2) Dissolve the contents of a vial of *desmopressin BPCRS* in a solution of 0.9% *sodium chloride* to give a final concentration of 0.01% w/v of the peptide.
(3) Dissolve the contents of a vial of *desmopressin impurity standard BPCRS* in 1 mL of a solution of 0.9% w/v *sodium chloride*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (12 cm × 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 1.5 mL per minute.
(d) Use an ambient column temperature.

(e) Use a detection wavelength of 220 nm.

(f) Inject 100 µL of each solution.

MOBILE PHASE

17 volumes of *acetonitrile* and 83 volumes of *0.067M mixed phosphate buffer solution, pH 7.0*.

SYSTEM SUITABILITY

The test is not valid unless:

in the chromatogram obtained with solution (3), the *resolution* between the two principal peaks is at least 2.0;

the peak due to desmopressin is clearly separated from any peaks due to the excipients stated on the label.

DETERMINATION OF CONTENT

Calculate the content of $C_{46}H_{64}N_{14}O_{12}S_2$ in the nasal spray 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 Nasal Spray should be protected from light and stored at a temperature of 2° to 8°, unless otherwise justified and authorised.

## IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Desmopressin.