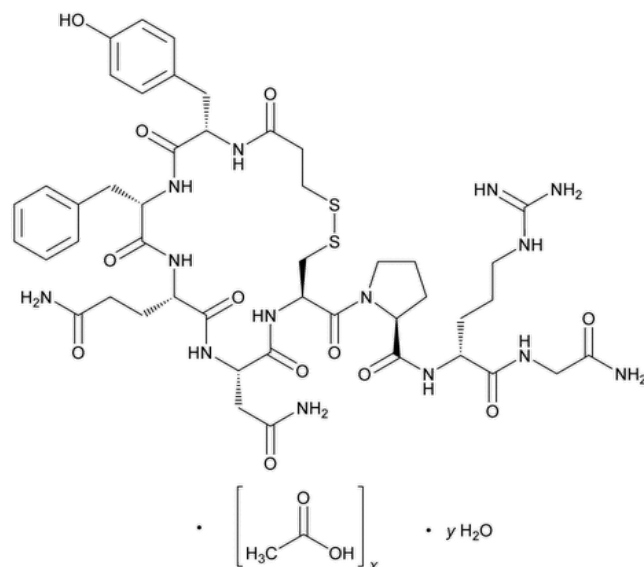


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Desmopressin Acetate



$\text{C}_{46}\text{H}_{64}\text{N}_{14}\text{O}_{12}\text{S}_2 \cdot x\text{C}_2\text{H}_4\text{O}_2 \cdot y\text{H}_2\text{O}$ 1069.22 (anhydrous, free base)
 Vasopressin, 1-(3-mercaptopropionic acid)-8-D-arginine-, acetate (salt) hydrate;
 1-(3-Mercaptopropionic acid)-8-D-arginine-vasopressin, acetate (salt) hydrate.
 x(acetate), y(water).

Monoacetate trihydrate CAS RN®: 62357-86-2; UNII: XB13HYU18U.

Monoacetate anhydrous CAS RN®: 62288-83-9; UNII: 1K12647SFC.

DEFINITION

Desmopressin Acetate is a synthetic octapeptide hormone having the property of antidiuresis. It is a synthetic analog of vasopressin. It contains NLT 95.0% and NMT 105.0% of desmopressin ($\text{C}_{46}\text{H}_{64}\text{N}_{14}\text{O}_{12}\text{S}_2$), calculated on the anhydrous, acetic acid-free basis.

IDENTIFICATION

- **A.** The monoisotopic mass by [Mass Spectrometry \(736\)](#) is 1068.4 ± 0.5 mass units.
- **B.**

Buffer solution, Mobile phase, Standard solution, and Sample solution: Prepare as directed in the Assay.

Identity sample solution: 10 µg/mL each of [USP Desmopressin Acetate RS](#) and Desmopressin Acetate in *Mobile phase*

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. The major peaks of the *Identity sample solution* coelute.

ASSAY

Change to read:

• PROCEDURE

Buffer solution: Dissolve 3.4 g of [monobasic potassium phosphate](#) and 2.0 g of [sodium 1-heptanesulfonic acid](#) in 1000 mL of [water](#). Adjust with [phosphoric acid](#) or [sodium hydroxide](#) to a pH of 4.50 ± 0.05 , as needed. Pass through a filter of 0.45-µm pore size.

Mobile phase: Mix [acetonitrile](#) and *Buffer solution* (22:78), and degas. Make adjustments, if necessary (see [Chromatography \(621\)](#), *System Suitability*). [NOTE—The retention time of desmopressin is very sensitive to the composition of the *Mobile phase*.]

Standard solution: 20 µg/mL of [USP Desmopressin Acetate RS](#) in *Mobile phase*

Sample solution: 20 µg/mL of Desmopressin Acetate in *Mobile phase*

System suitability solution: Dissolve about 1 mg of ▲[USP Oxytocin Identification RS](#)▲ (IRA 1-Mar-2021) accurately weighed, in a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Transfer 5.0 mL each of the resulting solution and the *Sample solution* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 50 μL

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between desmopressin and oxytocin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0% for the desmopressin peak area for replicate injections, *Standard solution*

Chromatogram similarity: The desmopressin peak elutes before the oxytocin peak, *System suitability solution*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of desmopressin ($C_{46}H_{64}N_{14}O_{12}S_2$) in the portion of Desmopressin Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Desmopressin Acetate RS](#) (calculated on the anhydrous, acetic acid-free basis) in the *Standard solution* (mg/mL)

C_U = concentration of Desmopressin Acetate (calculated on the anhydrous, acetic acid-free basis) in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0% on the anhydrous, acetic acid-free basis

IMPURITIES

• DESMOPRESSIN-RELATED IMPURITIES

Mobile phase and System suitability solution: Prepare as directed in the Assay.

Standard solution: 1 μg/mL of [USP Desmopressin Acetate RS](#) in *Mobile phase*, prepared by diluting 0.5 mL of the *Standard solution* from the Assay with *Mobile phase* to 10 mL

Sample solution: 200 μg/mL of Desmopressin Acetate in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 200 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between desmopressin and oxytocin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0% for the desmopressin peak area for replicate injections, *Standard solution*

Chromatogram similarity: The desmopressin peak elutes before the oxytocin peak, *System suitability solution*.

Analysis