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Desmopressin Acetate Injection

DEFINITION

Desmopressin Acetate Injection is a sterile solution of Desmopressin Acetate in a suitable diluent. It may contain suitable preservatives. It possesses, in each mL, an activity of NLT 90.0% and NMT 110.0% of the labeled amount of desmopressin ($C_{46}H_{64}N_{14}O_{12}S_2$), calculated on the anhydrous, acetic acid-free basis.

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer solution: Dissolve 4.9 g of phosphoric acid, accurately weighed, in water. Dilute with water to 1000 mL, and adjust with triethylamine to a pH of 3.5.

Solution A: Transfer 9 g of sodium chloride, accurately weighed, to a 1000-mL flask, and dissolve in and dilute with water to volume. Adjust with hydrochloric acid to a pH between 3.5 and 5.0.

Solution B: Transfer 9 g of sodium chloride, accurately weighed, to a 1000-mL flask, dissolve in water, and add 5 g of chlorobutanol. Dilute with water to volume, and adjust with hydrochloric acid to a pH between 3.5 and 5.0.

Mobile phase: Acetonitrile and *Buffer solution* (16.5:83.5). Filter and degas. Make adjustments, if necessary (see [Chromatography \(621\)](#), [System Suitability](#)).

Sample solution: For injections with concentrations of desmopressin between 4 µg/mL and 0.1 mg/mL, use undiluted Injection. For injections with concentrations exceeding 0.1 mg/mL and without preservatives, dilute 1000 µL of Injection, accurately measured, with 10 mL of *Solution A*. For injections with concentrations exceeding 0.1 mg/mL and containing preservatives, dilute 1000 µL of Injection, accurately measured, with 10 mL of *Solution B*.

Standard solution: 1 mg/mL of [USP Desmopressin Acetate RS](#) in water. Dilute with *Solution A* or *Solution B*, as directed in *Sample solution*, to obtain a solution with a concentration of desmopressin equivalent to that of the *Sample solution*.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 100 µL; 50 µL for *System suitability*

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.4

Relative standard deviation: NMT 5.0% for replicate injections

Analysis

Samples: *Sample solution* and *Standard solution*

Separately inject the *Sample solution* and the *Standard solution*, both freshly prepared, and record the chromatograms for a total time of NLT 2.5 times the retention time of the desmopressin peak.

Calculate the quantity of desmopressin ($C_{46}H_{64}N_{14}O_{12}S_2$), in mg, in the volume of Injection taken:

$$\text{Result} = C \times D \times (r_U/r_S)$$

C = concentration of [USP Desmopressin Acetate RS](#) in the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

Acceptance criteria: 90.0%–110.0% on the anhydrous, acetic acid-free basis

SPECIFIC TESTS

- **pH** (791): 3.5–6.0
- **BACTERIAL ENDOTOXINS TEST** (85): NMT 10 USP Endotoxin Units/μg of desmopressin
- **STERILITY TESTS** (71): It meets the requirements when tested as directed in [Test for Sterility of the Product to Be Examined, Membrane Filtration](#).
- **PARTICULATE MATTER IN INJECTIONS** (788): Meets the requirements for small-volume injections
- **OTHER REQUIREMENTS:** It meets the requirements in [Injections \(1\)](#), [Container Content](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light. Store at a temperature between 2° and 8°.
- **LABELING:** Label it to state the potency, in mg, of desmopressin.
- **USP REFERENCE STANDARDS** (11):
[USP Desmopressin Acetate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DESMOPRESSIN ACETATE INJECTION	Julie Zhang Associate Science & Standards Liaison	BIO12020 Biologics Monographs 1 - Peptides

Chromatographic Database Information: [Chromatographic Database](#)

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