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Desmopressin Nasal Spray Solution

DEFINITION

Desmopressin Nasal Spray Solution is a solution of Desmopressin Acetate in a suitable diluent. It is supplied in a form suitable for nasal administration and contains suitable preservatives. It contains 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. Dissolve in and dilute with water to volume. Adjust with hydrochloric acid to a pH of 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 of 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 nasal spray solutions with concentrations of desmopressin between 4 µg/mL and 0.1 mg/mL, use undiluted Nasal Spray Solution. For nasal spray solutions with concentrations exceeding 0.1 mg/mL and without preservatives, dilute 1000 µL of Nasal Spray Solution, accurately measured, with 10 mL of *Solution A*. For nasal spray solutions with concentrations exceeding 0.1 mg/mL and containing preservatives, dilute 1000 µL of Nasal Spray Solution, 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 the *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 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 Nasal Spray Solution 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

• **Microbial Enumeration Tests** ⟨61⟩and**Tests for Specified Microorganisms** ⟨62⟩**:** The total aerobic microbial count does not exceed 100 cfu/mL, the total combined molds and yeasts count does not exceed 10 cfu/mL, and it meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in containers suitable for administering the contents by spraying into the nasal cavities in a controlled, individualized dosage. Protect from light, and store at a temperature between 2° and 8°.

• **Labeling:** Label it to indicate that it is for intranasal administration only and to state the total number of discharges. Label it also to state that the dosage regulation is described in the package insert.

• **Uniformity of Unit Spray Weight and Total Number of Discharges per Container**

Samples: Three Nasal Spray Solution units

Analysis: Prime each spray pump as directed on the label, but NMT 5 times. Accurately weigh, by difference, 10 individual deliveries from each unit, weighing the first 3 discharges immediately after priming, 4 discharges from the middle of each unit, and 3 discharges close to the end of each unit. Continue to discharge until the unit is empty. For each unit, determine the total number of discharges, including the number of priming deliveries, and calculate the mean weight delivered per discharge.

Acceptance criteria: Each unit contains NLT the number of discharges stated on the label; the mean weight delivered per discharge is within 10% of the labeled weight per discharge; and NLT 9 tested discharges for each unit are between 85% and 125% of the labeled weight per discharge.

• **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 NASAL SPRAY SOLUTION	Julie Zhang Associate Science & Standards Liaison	BIO12020 Biologics Monographs 1 - Peptides

Chromatographic Database Information: Chromatographic Database

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