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Vasopressin

* in pig vasopressin, R is K

$C_{46}H_{65}N_{15}O_{12}S_2$ 1084.24

Vasopressin, 8-L-arginine CAS RN®: 113-79-1; UNII: Y4907O6MFD.

DEFINITION

Vasopressin is a polypeptide hormone having the properties of causing the contraction of vascular and other smooth muscles, and of antidiuresis. It is prepared by chemical synthesis. It contains NLT 95.0% and NMT 105.0% of vasopressin ($C_{46}H_{65}N_{15}O_{12}S_2$), calculated on the anhydrous, acetic acid-free basis.

IDENTIFICATION

- **A.** The retention time of the vasopressin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B. Mass Spectral Analysis**

Infusion solution: Acetonitrile, water, and trifluoroacetic acid (80:20:0.08)

Standard solution: 1 mg/mL of USP Vasopressin RS in water

Sample solution: 1 mg/mL of Vasopressin in water.

[Note—The final concentrations of the *Standard solution* and the *Sample solution* can be adjusted, depending on the sensitivity of the mass spectrometer used in the testing.]

Instrumental conditions

(See *Mass Spectrometry ⟨736⟩*.)

Mode: LC/MS spectrometer

Interface/detection: Infusion system connected to an electrospray interface (positive ion)

Flow rate: 0.3 mL/min

Injection size: 10 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: Should contain peaks with mass-to-charge ratios of 1084 and 543

ASSAY

- **Procedure**

Mobile phase: Dissolve 6.6 g of dibasic ammonium phosphate in 950 mL of water. Adjust with concentrated phosphoric acid to a pH of 3.0. Dilute with water to 1000 mL. To 870 mL of this solution add 130 mL of acetonitrile, and mix. Filter under vacuum through a nylon membrane of 0.45-µm pore size. [Note—The retention time of the vasopressin peak is very sensitive to small changes in acetonitrile concentration in the *Mobile phase*.]

System suitability solution: Dissolve suitable quantities of USP Lypressin RS and USP Vasopressin RS in 0.25% glacial acetic acid to obtain a solution having a known concentration of about 25 µg/mL of each substance.

Standard solution: Dissolve the entire contents of a vial of USP Vasopressin RS in a known volume of 0.25% glacial acetic acid. [Note—The solution may be diluted as necessary to a working concentration range for the *Assay*.]

Sample solution: Transfer about 10 mg of Vasopressin to a 25-mL volumetric flask. Dissolve in 0.25% glacial acetic acid, and dilute with the same solvent to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 40 ± 1°

Flow rate: 1.0 mL/min

Injection size: 20 µL. [NOTE—The column is allowed to equilibrate for 1 h before making the first injection.]

System suitability

Samples: *System suitability solution* and *Standard solution*. [NOTE—Inject into an equilibrated liquid chromatograph, allowing about 60 min for complete elution.]

[NOTE—The retention time of the vasopressin peak is between 6 and 9 min.]

Suitability requirements

Resolution: NLT 1.1 between the vasopressin and lypressin peaks

Relative standard deviation: NMT 2.0% for the vasopressin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of vasopressin ($C_{46}H_{65}N_{15}O_{12}S_2$) in the portion of Vasopressin 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 Vasopressin RS in the *Standard solution* (mg/mL)

C_U = concentration of Vasopressin in the *Sample solution* (mg/mL)

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

IMPURITIES

• **ORDINARY IMPURITIES:** The sum of the responses of impurities from the *Sample solution* in the *Assay* is NMT 5% of the area of the vasopressin peak.

SPECIFIC TESTS

• **MICROBIAL ENUMERATION TESTS ⟨61⟩** and **TESTS FOR SPECIFIED MICROORGANISMS ⟨62⟩:** The total bacterial count is NMT 2×10^2 cfu/g. For products of animal origin, it also meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

• **WATER DETERMINATION, *Method Ic*⟨921⟩:** NMT 8.0%

• **ACETIC ACID IN PEPTIDES ⟨503⟩:** NMT 15.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, preferably of Type I glass, and store in a refrigerator.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Lypressin RS

USP Vasopressin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
VASOPRESSIN	Jennifer Tong Sun Senior Scientist II	BIO12020 Biologics Monographs 1 - Peptides
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO12020 Biologics Monographs 1 - Peptides

Chromatographic Database Information: Chromatographic Database

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