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Vasopressin Injection

» Vasopressin Injection is a sterile solution of Vasopressin in a suitable diluent. Each mL of Vasopressin Injection possesses an activity of not less than 90.0 percent and not more than 110.0 percent of that stated on the label in USP Vasopressin Units. It may contain a suitable preservative.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Do not freeze.

Labeling—Label it to indicate its origin (animal or synthetic). Label it also to state the potency in USP Vasopressin Units per mL.

USP REFERENCE STANDARDS (11)—

[USP Vasopressin RS](#)

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 17.0 Endotoxin Units per USP Vasopressin Unit.

pH (791): between 2.5 and 4.5.

PARTICULATE MATTER IN INJECTIONS (788)—It meets the requirements under small-volume injections.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Mobile phase, System suitability solution, Chromatographic system, and Procedure—Proceed as directed in the Assay under [Vasopressin](#).

Diluent—Dissolve 5.0 g of chlorobutanol in 5.0 mL of glacial acetic acid, add 5.0 g of alcohol, 1.1 g of sodium acetate, and 1000 mL of water, and mix.

Standard preparation—Dissolve the entire contents of a vial of [USP Vasopressin RS](#) in a known volume of *Diluent*. [NOTE—The solution may be diluted as necessary to a working concentration range for the Assay.]

Assay preparation—Pipet 2.0 mL of Injection into a 25-mL volumetric flask, dilute with 0.25% glacial acetic acid to volume, and mix.

Procedure—Calculate the potency, in USP Vasopressin Units per mL, by the formula:

$$C(r_u/r_s)$$

in which *C* is the concentration, in USP Vasopressin Units per mL, of the *Standard preparation*; and r_u and r_s are the mean values of the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively. [NOTE—The runtime should be long enough to allow for the elution of the chlorobutanol peak (approximately 60 minutes).]

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

Topic/Question	Contact	Expert Committee
VASOPRESSIN INJECTION	Julie Zhang Associate Science & Standards Liaison	BI012020 Biologics Monographs 1 - Peptides
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BI012020 Biologics Monographs 1 - Peptides

Chromatographic Database Information: [Chromatographic Database](#)

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