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Arginine Hydrochloride Injection

» Arginine Hydrochloride Injection is a sterile solution of Arginine Hydrochloride in Water for Injection. It contains not less than 9.5 percent and not more than 10.5 percent of $C_6H_{14}N_4O_2 \cdot HCl$. It contains no antimicrobial agents.

[NOTE—The chloride ion content of Arginine Hydrochloride Injection is approximately 475 mEq per L.]

Packaging and storage—Preserve in single-dose containers, preferably of Type II glass.

USP REFERENCE STANDARDS (11)—
[USP Arginine Hydrochloride RS](#)

Labeling—The label states the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.

Identification—

A: Transfer 1 mL of the Injection to a 200-mL volumetric flask, and dilute with water to volume. To 1 mL of this dilution add 2 mL of a solution of 0.02% 8-hydroxyquinoline in 3 N sodium hydroxide, and add 1 mL of 0.1% *N*-bromosuccinimide solution: an orange color is produced.

B: It meets the requirements of the tests for [Chloride \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.01 USP Endotoxin Unit per mg of arginine hydrochloride.

pH (791): between 5.0 and 6.5.

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

Assay—

Color reagent—Dissolve 28.0 g of potassium hydroxide and 2.0 g of potassium sodium tartrate in 100 mL of water. Cool, and add, in the order named, 100 mg of 2,4-dichloro-1-naphthol, 180 mL of alcohol, and 20.0 mL of 0.475% sodium hypochlorite solution. Mix by swirling, and allow to stand at room temperature for 1 hour before using. This *Color reagent* may be stored in a glass-stoppered bottle, in a refrigerator, for 2 months.

Standard preparation—Dissolve an accurately weighed quantity of [USP Arginine Hydrochloride RS](#) in water, and dilute quantitatively and stepwise with water to obtain a solution having a known concentration of about 40 µg per mL.

Assay preparation—Pipet into a 100-mL volumetric flask a volume of Injection, equivalent to 200 mg of arginine hydrochloride, add water to volume, and mix. Pipet 5 mL of this solution into a 250-mL volumetric flask, add water to volume, and mix.

Procedure—Transfer 2.0-mL portions of the *Assay preparation* and the *Standard preparation*, respectively, to separate flasks, and treat each as follows. Add 2.0 mL of potassium iodide solution (3 in 1000), mix, and allow to stand for 15 minutes. Add 6.0 mL of *Color reagent*, mix, and allow to stand for 15 minutes. Add 2.0 mL of sodium hypochlorite solution (19 in 10,000), mix, and allow to stand for 15 minutes.

Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 520 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of $C_6H_{14}N_4O_2 \cdot HCl$ in each mL of the Injection taken by the formula:

$$5(C/V)(A_u/A_s)$$

in which *C* is the concentration, in µg per mL, of [USP Arginine Hydrochloride RS](#) in the *Standard preparation*; *V* is the volume, in mL, of Injection taken; and *A_u* and *A_s* are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
ARGININE HYDROCHLORIDE INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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