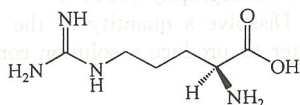


Category As described under Aprotinin.

Strength (1) 28 Units (50 000 KIU)
(2) 56 Units (100 000 KIU)
(3) 112 Units (200 000 KIU)
(4) 278 Units (500 000 KIU)

Storage Preserve in well closed containers, stored in a cool place and protected from light.

Arginine



$C_6H_{14}N_4O_2$ 174.20 [74-79-3]

Arginine is L-2-Amino-5-guanidopentanoic acid. It contains not less than 99.0% of $C_6H_{14}N_4O_2$, calculated on the dried basis.

Description White crystals or a crystalline powder; almost odourless; taste, characteristic. Freely soluble in water, practically insoluble in ethanol, freely soluble in dilute hydrochloric acid.

Specific optical rotation +26.9° to +27.9°, in a solution of 80 mg per ml in 6 mol/L hydrochloric acid solution <0621>.

Identification (1) Dissolve separately a quantity of the substance being examined and arginine CRS in 0.1 mol/L hydrochloric acid solution to produce solutions each of 10 mg per ml as the test solution and the reference solution. Use the chromatographic conditions described under the Other amino acids. The position and colour of the principal spot in the chromatogram obtained with the test solution correspond to that of the principal spot obtained with the reference solution.

(2) The infrared absorption spectrum <0402> is concordant with the reference spectrum (IR Album No. 1075).

Alkalinity Dissolve 2.5 g of the substance being examined in 25 ml of water, pH 10.5-12.0 <0631>.

Transmittance of solution Dissolve 1.0 g of the substance being examined in 10 ml of water, measure the transmittance at 430 nm <0401>, not less than 98.0%.

Chlorides Carry out the limit test for chlorides <0801>, using 0.30 g of the substance being examined. Any opalescence produced is not more pronounced than that of a reference solution prepared using 6.0 ml of sodium chloride standard solution (0.02%).

Sulfates Carry out the limit test for sulfates <0802>, using 1.0 g of the substance being examined. Any opalescence produced is not more pronounced than that of a reference solution prepared using 2.0 ml of potassium sulfate standard solution (0.02%).

Ammonium Carry out the limit test for ammonium <0808>, using 0.10 g of the substance being examined. Any colour produced is not more intense than that of a reference solution prepared using 2.0 ml of ammonium chloride standard solution (0.02%).

Proteins Dissolve 1 g of the substance being examined in 10 ml of water, add 5 drops of 20% trichloroacetic acid, no precipitate is produced.

Other amino acids Carry out the method for thin-layer chromatography <0502>.

Solvent 0.1 mol/L hydrochloric acid solution.

Test solution Dissolve a quantity of the substance being examined in solvent to produce a solution of about 10 mg per ml.

Reference solution Measure accurately 1 ml of the test solution to a 250 ml volumetric flask, dilute with solvent to volume and mix well.

System suitability solution Dissolve separately a quantity of arginine CRS and lysine hydrochloride CRS in solvent to produce a solution containing 10 mg of arginine and 0.4 mg of lysine hydrochloride per ml.

Chromatographic conditions Use silica gel G as the coating substance and a mixture of *n*-propanol-concentrated ammonia solution (6 : 3) as the mobile phase.

Procedure Apply separately to the plate 5 µl of each of the above three solutions. After developing 20 cm, remove the plate, dry in air, heat at 90°C for 10 minutes, cool and spray with a solution of 1% ninhydrin in *n*-propanol, heat at 90°C until the spots are produced. Examine the spots immediately.

System suitability requirements The chromatogram obtained with the reference solution shows a clearly visible spot. The chromatogram obtained with the system suitability solution shows two clearly separated spots.

Limits Any spot other than the principal spot obtained with the test solution is not more intense than the principal spot obtained with the reference solution (0.4%). Not more than one such spot is observed.

Loss on drying When dried at 105°C for 3 hours, loses not more than 0.5% of its weight <0831>.

Residue on ignition Not more than 0.1% <0841>.

Iron Carry out the limit test for iron <0807>, using 1.0 g of the substance being examined. Any colour produced is not more intense than that of a reference solution prepared using 1.0 ml of iron standard solution (0.001%).

Heavy metals Dissolve 1.0 g of the substance being examined in 23 ml of water and 2 ml of acetate BS (pH 3.5). Carry out the limit test for heavy metals <0821, method 1>; not more than 0.001%.

Arsenic Dissolve 2.0 g of the substance being examined in 23 ml of water, add 5 ml of hydrochloric acid. Carry out the limit test for arsenic <0822, method 1>; not more than 0.0001%.

Bacterial endotoxins Carry out the test for bacterial endotoxins <1143>; less than 10 EU per g of Arginine. (for parenteral use)

Assay Dissolve about 80 mg of the substance being examined, accurately weighed, in 3 ml of anhydrous formic acid, add 50 ml of glacial acetic acid. Carry out the method for potentiometric titration <0701>, titrate with perchloric acid (0.1 mol/L) VS. Perform a blank determination and make any necessary correction. Each ml of perchloric acid (0.1 mol/L) VS is equivalent to 8.710 mg of $C_6H_{14}N_4O_2$.

Category Amino acid.

Storage Preserve in tightly closed containers.