L-Tyrosine[1]

$C_9H_{11}NO_3$: 181.19

L-Tyrosine, when dried, contains not less than 99.0 percent and not more than 101.0 percent of L-Tyrosine ($C_9H_{11}NO_3$).

Description

White crystals or crystalline powder.
Freely soluble in formic acid, practically insoluble in water and in ethanol (99.5).
Dissolves in dilute hydrochloric acid and in ammonia T.S..

Identification

(1) Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.
(2) Determine the absorption spectrum of a solution of the sample in 0.1mol/L hydrochloric acid (1 in 10000) as directed under Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelength.

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	-11.3 to -12.1°	AJI TEST 1 [Dried sample, C=5, 1mol/L HCl][2]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 20mL of 1mol/L HCl, spectrophotometer, 430nm, warming, 10mm cell thickness]
Chloride (Cl)	Not more than 0.020%	AJI TEST 3 [0.5g, A-1, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [D-1]
Sulfate (SO_4)	Not more than 0.020%	AJI TEST 5 [0.85g, (2), ref: 0.35mL of 0.005mol/L H_2SO_4]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [1.0g, A-3, ref: 1.0mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (4), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	Not more than 1ppm	AJI TEST 8 [2.0g, (2), ref: 2.0mL of As_2O_3 Std.]
Related substances	1)Conforms[3] 2) Phenylalanine Not more than 0.50% Any unspecified impurity Not more than 0.20% Total impurities Not more than 0.60%	AJI TEST 9 [Dilute ammonia R2[4], test sample: 50μg, F-6-a, control; L-Tyr 0.25μg] AJI TEST 26[5]

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Specifications (cont'd)

Item	Limit	Test
Loss on drying	Not more than 0.20%	AJI TEST 11 [1g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g, at 550°C to 650°C for 3 hours]
Assay	99.0 to 101.0%	AJI TEST 14 [Dried sample, 180mg, (1), 6mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=18.12mg $C_9H_{11}NO_3$]
pH	5.0 to 6.5	AJI TEST 33 [0.02g in 50mL (saturated aqueous solution)]

The test for Endotoxin when the material will be used for manufacturing parenteral products is as follows:

Item	Limit	Test
Endotoxin	Less than 6.0EU/g	AJI TEST 34 [C=1, ultrafiltration, kinetic-turbidimetric technique]

[1] This product, in terms of actual quality, conforms to USP, EP, and JP.

[2] Temperature coefficient of $[\alpha]_D^t$: +0.26°

[3] Any secondary spot in the chromatogram obtained from the Test Solution is less intense than the principal spot in the chromatogram obtained from the Standard Solution: the number of those spots is not more than four and not more than 2.0% of the total impurities found.

[4] Dilute ammonia R2: 33g/L~35g/L

[5] Disregard limit: 0.05%

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