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N-Acetyl-L-Tyrosine (for Europe)		
Issued Date: Sep. 5, 2014		

N-Acetyl-L-Tyrosine¹

C₁₁H₁₃NO₄: 223.23

N-Acetyl-L-tyrosine, when dried, contains not less than 99.0 percent and not more than 101.0 percent of N-Acetyl-L-tyrosine (C₁₁H₁₃NO₄).

Description

White crystals or crystalline powder; strongly acid taste.
Freely soluble in water.

Identification

Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.

Specifications

Item	Limit	Test
Specific rotation [α] _D ²⁰	+46.5 to +49.0°	AJI TEST 1 [Dried sample, C=1, H ₂ O]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 20mL of H ₂ O, spectrophotometer, 430nm, 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 [B-1]
Sulfate (SO ₄)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H ₂ SO ₄]
Iron (Fe)	Not more than 20ppm	AJI TEST 6 [0.38g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, weakly acidic, (1), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As ₂ O ₃)	Not more than 2ppm	AJI TEST 8 [1.0g, (1), ref: 2.0mL of As ₂ O ₃ Std.]
Related substance	Not more than 0.80% of tyrosine Not more than 0.10% of unspecified impurities Not more than 1.0% of total	[HPLC(EP method)] ²
Loss on drying	Not more than 0.50%	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]

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Specifications (cont'd)

Item	Limit	Test
Assay	99.0 to 101.0%	AJI TEST 17 [Dried sample, 300mg, 40mL of H ₂ O, (2), 0.1mol/L NaOH 1mL=22.32mg C ₁₁ H ₁₃ NO ₄]
pH	2.0 to 3.0	AJI TEST 33 [1.25g in 50mL of H ₂ O]

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

Item	Limit	Test
Endotoxin	Less than 25.0EU/g	AJI TEST 34 [C=0.24, kinetic-turbidimetric technique]

¹ This product, in terms of actual quality, conforms to EP.

² HPLC (EP method)
Disregard limit:0.05%

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