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N-Acetyl-DL-Tryptophan		
Issued Date: Jun. 14, 2019		

N-Acetyl-DL-tryptophan¹

C₁₃H₁₄N₂O₃: 246.26

N-Acetyl-DL-tryptophan, when dried, contains not less than 99.0 percent and not more than 101.0 percent of N-Acetyl-DL-tryptophan (C₁₃H₁₄N₂O₃).

Description

White crystals or crystalline powder; strongly acid taste.

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	-1.0 to +1.0°	AJI TEST 1 [Dried sample, C=10, 1mol/L NaOH]
Optical rotation α _D ²⁰	-0.1 to +0.1°	AJI TEST 1 [Dried sample, C=10, 1mol/L NaOH]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 50mL of 1mol/L NaOH, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	Not more than 0.040%	AJI TEST 3 [0.25g, A-7, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH ₄)	Not more than 0.02%	AJI TEST 4 [A-3]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [0.75g, B-2, ref: 0.75mL 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 ₂ O ₃)	Not more than 2ppm	AJI TEST 8 [1.0g, (5), ref: 2.0mL of As ₂ O ₃ Std.]
Related substances	Not more than 0.25% of other impurity (each) Not more than 0.5% of total impurities	[EP]
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]
Assay	99.0 to 101.0%	AJI TEST 17 [Dried sample, 350mg, methanol 30mL+H ₂ O 20mL, (2), 0.1mol/L NaOH 1mL=24.63mg C ₁₃ H ₁₄ N ₂ O ₃]
pH	2.5 to 3.5	AJI TEST 33 [1.0g in 100mL (saturated aqueous solution)]

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

Item	Limit	Test
Endotoxin	Less than 50.0EU/g	AJI TEST 34 [C=0.25, kinetic-turbidimetric technique]

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

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