N-Acetyl-DL-tryptophan[1]

$C_{13}H_{14}N_2O_3$: 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 ($C_{13}H_{14}N_2O_3$).

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 $[\alpha]_D^{20}$	-1.0 to +1.0°	AJI TEST 1 [Dried sample, C = 10, 1 mol/L NaOH]
Optical rotation α_D^{20}	-0.1 to +0.1°	AJI TEST 1 [Dried sample, C = 10, 1 mol/L NaOH]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5 g in 50 mL of 1 mol/L NaOH, spectrophotometer, 430 nm, 10 mm cell thickness]
Chloride (Cl)	Not more than 0.040%	AJI TEST 3 [0.25 g, A-7, ref: 0.28 mL of 0.01 mol/L HCl]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [A-3]
Iron (Fe)	Not more than 10 ppm	AJI TEST 6 [0.75 g, B-2, ref: 0.75 mL of Iron Std. (0.01 mg/mL)]
Heavy metals (Pb)	Not more than 10 ppm	AJI TEST 7 [1.0 g, (4), ref: 1.0 mL of Pb Std. (0.01 mg/mL)]
Arsenic (As_2O_3)	Not more than 2 ppm	AJI TEST 8 [1.0 g, (5), ref: 2.0 mL of As_2O_3 Std.]
Related substances	Any unspecified impurity Not more than 0.25% Total impurities Not more than 0.50%	HPLC[2]
Loss on drying	Not more than 0.50%	AJI TEST 11 [1 g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1 g, at 550°C to 650°C for 3 hours]
Assay	99.0 to 101.0%	AJI TEST 17 [Dried sample, 350 mg, methanol 30 mL+H_2O 20 mL, (2), 0.1 mol/L NaOH 1 mL = 24.63 mg $C_{13}H_{14}N_2O_3$]
pH	2.5 to 3.5	AJI TEST 33 [1.0 g in 100 mL (saturated aqueous solution)]

Specifications (cont'd)

Item	Limit	Test
Microbial Test Total aerobic microbial count (TAMC)	Not more than 100 cfu/g	AJI TEST 28 [MF method, 1 g/500 mL, Chloride-Peptone Solution pH 7.0]
Total combined yeasts/ molds count (TYMC)	Not more than 10 cfu/g	AJI TEST 28 [MF method, 1 g/500 mL, Chloride-Peptone Solution pH 7.0]

The following test item is added for parenteral products:

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

[1] This product, in terms of actual quality, conforms to USP and EP.
[2] This test method conforms to USP and EP.
Disregard limit: 0.01%

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