

ALADDIN SCIENTIFIC CORPORATION

14078 Meridian Parkway, Riverside, CA. 92518

Specification Sheet

Product Name: **L-Tryptophan**
 Specifications & Purity: PharmPure™, USP, JP, BP, Ph.Eur.
 SKU #: **L774650**

Parameter	Limit Values
Appearance(L774650)	White or almost white, crystalline or amorphous powder
Solubility : sparingly soluble in water, slightly soluble in ethanol (96 per cent). It dissolves in dilute solutions of mineral acids and alkali hydroxides	Pass
Assay(Perchloric acid titration, calc. on anhydrous substance)	98.5-101 (%)
Identity (IR-spectrum)	conforms
Identity(specific rotation)	Pass
Identity(TLC)	Passes test
Identify(EP)(D)	Pass
Appearance of solution(10 g/l, 1M HCl),clear and not more intense in color than reference solution BY6	Pass
Specific Rotation [a] ₂₀ /D(c=1 in H ₂ O)(calcd.on anh.substance)	-33~-30 (°)
Specific Rotation [a] ₂₅ /D(C=1 in H ₂ O, calc. on dried substanc)	-32.8~-29.4 (°)
pH(10 g/l,CO ₂ -free water)	5.5-6.4
Ninhydrin-positive substances(LC)(any ninhydrin-positive impurity)	0-0.2 (%)
Ninhydrin-positive substances(LC)(ammonium(570nm)	0-0.02 (%)
Ninhydrin-positive substances(LC)(total impurities)	0-0.5 (%)
Impurity A((1,1'-ethylidenebistryptophan)	0-10 (ppm)
Sum of impurities with RT < tryptophan-peak	0-100 (ppm)
Sum of impurities with RT > tryptophan-peak and up to1,8 times the RT ofacetyltryptophan	0-300 (ppm)
Chloride(Cl)	0-200 (ppm)
Sulfate(SO ₄)	0-280 (ppm)
Heavy metals	0-20 (ppm)
Fe(iron)	0-20 (ppm)
Arsenic(As)	0-2 (ppm)
loss on drying(105°C,3 h)	0-0.3 (%)
Residue on Ignition	0-0.1 (%)
Related substances (HPLC)	Passes test
Related substances(TLC)	passes test
Other amino acids (TLC)	0-0.5 (%)
Transmittance of Solution (25 g/l, Hydrochloric Acid 2 mol/l)	95-100 (%)

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Parameter

Residual solvents (ICH (Q3C))excluded by manufacturing process

Bacterial endotoxins

Microbiological test(total aerobic microbial count(TAMC))

Microbiological test(total yeast and mould count(TYMC))

Ethanol

Limit Values

pass

0-10 (IU/g OR u/g)

0-100 (CFU/g)

0-100 (CFU/g)

< 5000 (ppm)