Certificate of Analysis

Certificate n.:	2722		
INN:	L-5-Hydroxytryptophan		
Code:	ITR1	Manufacturing date:	10-07-2019
Batch:	21002	Expiry date:	10-07-2024
Net weight:	30.00 KG	Order Number:	OC0000571

Test	Result	Method	Limits
Appearance	Complies	In-house (visual)	White to grey white powder
Loss on drying	0.5 %	Ph. Eur. (2.2.32) current ed.	Not more than 2.0 %
pH	5.6	Ph. Eur. (2.2.3) current ed.	Between 4.0 and 6.0
Solubility	Complies	In-house	Slightly soluble in water, insoluble in organic solvents
Specific optical rotation	-32.6	Ph. Eur. (2.2.7) current ed.	Between -38.0 and -30.0
Related substances:		In-house (HPLC)	
L-tryptophan	0.1 %		Not more than 0.2 %
Any unspecified impurity (max single)	<0.05 %		Not more than 0.10 %
Total	0.1 %		Not more than 0.5 %
Assay (dried substance)	100.7 %	In-house (potentiometric titration)	Between 99.0 and 101.0 %
Identification (IR)	Complies	Ph. Eur. (2.2.24) current ed.	Complies with reference standard
Sulfated ash	0.0 %	Ph. Eur. (2.4.14) current ed.	Not more than 0.2 %
Heavy metals	Complies	Ph. Eur. (2.4.8 - method C) current ed.	Not more than 10 ppm
Residual solvents:		In-house (GC)	
Methanol	46 ppm		Not more than 1000 ppm
Terz-butylmetylether	<5 ppm		Not more than 100 ppm
Tapped density	0.53 g/ml	Ph. Eur. (2.9.15) current ed.	Not less than 0.40 g/ml
Total aerobic microbial count	<10 CFU/g	Ph. Eur. (2.6.12) current ed.	Not more than 10^3 CFU/g
Total combined yeast/mould count	<10 CFU/g	Ph. Eur. (2.6.12) current ed.	Not more than 10^2 CFU/g
Bile-tolerant Gram-negative bacteria	0 CFU/g	Ph. Eur. (2.6.13) current ed.	Not more than 10^2 CFU/g
Escherichia coli	Complies	Ph. Eur. (2.6.13) current ed.	Absent/10g
Salmonella	Complies	Ph Eur. (2.6.31) current ed.	Absent/25g

Linnea SA - Via Cantonale - 6595 Riazzino Switzerland

T +41 (0)91 850 5050 - F +41 (0)91 850 5070 - info@linnea.ch - linnea.ch

Certificate of Analysis

Certificate n.:	2722		
INN:	L-5-Hydroxytryptophan		
Code:	ITR1	Manufacturing date:	10-07-2019
Batch:	21002	Expiry date:	10-07-2024
Net weight:	30.00 KG	Order Number:	OC0000571

Approved

Release date and time: 16-02-2021 13:36:28

Quality Unit Manager

Giorgia Tossi

The electronic signature used to release the lot is equivalent to a handwritten signature due to the compliance of the software used, to the international rules concerning electronic records and electronic signature management (FDA CFR21 p11, EU Annex 11).

Linnea SA - Via Cantonale - 6595 Riazzino Switzerland

T +41 (0)91 850 5050 - F +41 (0)91 850 5070 - info@linnea.ch - linnea.ch