Linnea
Natural Pharma Solutions

Certificate of Analysis

Certificate n.:	4059		
INN:	L-5-Hydroxytryptophan		
Code:	ITR1	Manufacturing date:	27-04-2023
Batch:	23001	Expiry date:	27-04-2028
Net weight:	60.00 KG	Order Number:	OC0000985

Test	Result	Method	Limits
Appearance	Complies	In-house (visual)	White to grey white powder
Loss on drying	0.4 %	Ph. Eur. (2.2.32) current ed.	Not more than 2.0 %
pH	5.7	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	-33.2	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)	100.1 %	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	39 ppm		Not more than 1000 ppm
Terz-butylmetylether	<5 ppm		Not more than 100 ppm
Tapped density	0.54 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

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The Batch has been manufactured and controlled in accordance with the requirements of GMPs and meets the Specifications

Approved

Release date and time (UTC): 26-05-2023 14:34:00

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).

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