

Certificate of Analysis

Certificate n.:	1616		
INN:	L-5-Hydroxytryptophan		
Code:	ITR1	Manufacturing date:	07-2019
Batch:	50819003	Expiry date:	07-2024
Net weight:	25.00 KG	Order Number:	OC0000053

<u>Test</u>	<u>Result</u>	<u>Method</u>	<u>Limits</u>
Appearance	Complies	In-house (visual)	White to grey white powder
Loss on drying	1.1 %	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	-32.7	Ph. Eur. (2.2.7) current ed.	Between -38.0 and -30.0
Related substances:		In-house (HPLC)	
<i>L-tryptophan</i>	0.1 %		Not more than 0.2 %
<i>Any unspecified impurity (max single)</i>	<0.05 %		Not more than 0.10 %
<i>Total</i>	0.1 %		Not more than 0.5 %
Assay (dried substance)	99.6 %	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	0.1 %	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)	
<i>Methanol</i>	126 ppm		Not more than 1000 ppm
<i>Terz-butylmetylether</i>	<5 ppm		Not more than 100 ppm
Tapped density	0.57 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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Approved

Release date and time: 07-11-2019 14:12:10

Quality Unit Manager

Giorgia Tossi

The digital 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).