

Certificate of analysis

Product name: **L-5-Hydroxytryptophan**
 Description: *L-5-Hydroxytryptophan*
 Code: ITR
 Batch: 50815001
 Net Weight: 50.00 Kg

Certificate n. 050473
 Date of manufacture: 06-2015
 Date of expiry: 06-2020

<u>Parameters</u>	<u>Results</u>	<u>Units</u>	<u>Method</u>	<u>Specifications</u>
Aspect	Complies	--	Internal Method	White to grey white powder
IR Identification	Complies	--	Internal Method	Complies with reference standard
pH	5.7	—	Internal Method	Between 4.0 and 6.0
Solubility	Complies	—	Internal Method	Slightly soluble in water, insoluble in organic solvents
Loss on drying	0.5	%	Internal Method	Not more than 2.0 %
Specific Optical Rotation	-33.0	°	Internal Method	Between -38.0 and -30.0
Assay (HClO ₄ titration)	100.1	%	Internal Method	Between 99.0 % and 101.0 %
Related substances:				
<i>L-tryptophan</i>	0.1	%		Not more than 0.2 %
<i>Total impurities</i>	0.2	%	Internal Method	Not more than 0.5 %
Sulphated ash	0.0	%	2.4.14 Ph Eur, current edition	Not more than 0.2 %
Heavy metals	Complies	—	2.4.8 Ph Eur, current edition	Not more than 15 ppm
Residual solvents:				
<i>Methanol</i>	102	ppm	Internal Method according to EP monograph 5.4	Not more than 1000 ppm
<i>Methyl t-butyl ether</i>	<5	ppm	Internal Method according to EP monograph 5.4	Not more than 100 ppm
Informative parameter:				
Tapped density	0.56	g/ml	2.9.15 Ph Eur, current edition	Preferible: Not less than 0.40 g/ml

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Microbiology				
<i>Total aerobic microbial count</i>	Complies	—	2.6.12 Ph Eur, current edition	Not more than 10 ³ cfu/g
<i>Total combined yeast/mould count</i>	Complies	—	2.6.12 Ph Eur, current edition	Not more than 10 ² cfu/g
<i>Escherichia coli</i>	Complies	—	2.6.13 Ph Eur, current edition	Absent/10 g
<i>Bile tolerant Gram-negative bacteria</i>	Complies	—	2.6.13 Ph Eur, current edition	Not more than 10 ² cfu/g
<i>Salmonella</i>	Complies	—	2.6.13 and 2.6.31 Ph Eur, current edition	Absent/25 g

Remarks:

Released on: 24.08.2015

Order Number: 15/294

APPROVED

Quality Unit Manager
 Giorgia Tossi

