

CERTIFICATE OF ANALYSIS

Product : **L-ISOLEUCINE**
 Product number : 10711
 Batch number : 012774
 Date of analysis : 24-02-2017
 Date of expiry : 31-01-2019
 Packaging and storage : in a well closed container

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white or almost white crystalline powder or flakes	complies		
Solubility	sparingly soluble in water, slightly soluble in alcohol, it dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	complies		
Appearance of solution	clear and colour $\leq$ ref. sol. BY ₆	complies		
Identification	conform	complies		IR-spectrum
Specific rotation	+40.0 – +43.0	+40.4	°	dried substance
Related substances	conform	complies		HPLC
Impurity A	≤ 0.3	0,1	%	
Impurity C	≤ 0.3	< 0.3	%	
Any other impurities	≤ 0.2	< 0.2	%	
Total impurities	≤ 1.0	0.2	%	
Chlorides	≤ 200	complies	ppm	
Sulfate	≤ 300	complies	ppm	
Ammonium	≤ 0.02	< 0.02	%	
Iron	≤ 10	complies	ppm	
Heavy metals	≤ 10	complies	ppm	
Loss on drying	≤ 0.5	0.0	%	105°C
Residue on ignition	≤ 0.1	0.0	%	
Assay	98.5 – 101.0	100.2	%	dried substance, titration

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 08-03-2017

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 S. de Bree

The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.