

Certificate of Analysis

Product name: **Leucinum apyrogen**
Batch number / Weight: **20J15-B02-210301 / 100 G**
Analysed according to: **Ph.Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or shining flakes	Conform		
Identification A	+14,5 - +16,5	Conform		Specific optical rotation
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=BY6	Conform		5% <i>m/V</i> HCl 1M
Specific optical rotation	+14,5 - +16,5	16,0	Å°	4% <i>m/V</i> HCl 25%, dried
Ninhydrin-positive substances	Conform	Conform		
Impurity A at 570 nm	<=0,8	<0,05	%	
Any ninhydrin-positive substance	<=0,2	0,2	%	
Ammonium at 570 nm	<=0,02	<0,02	%	
Total	<=1,0	0,2	%	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	Conform	ppm	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,02	%	105 °C
Sulphated ash	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Leucine	98,5 - 101,0	99,76	% <i>m/m</i>	Dried
Endotoxins	<6	Conform	IU / g	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

15-04-2021

Expiration: 23-08-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.