

Certificate of Analysis

Productname: Valinum apyrogéen
Number of analysis/Inspection Code: 1 / KEUR-180667B
Batchnumber: 18B27-B05-367295
Reference code / No.: 3968 / 172241
Analysed according to: PH.EUR 9.3

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Fermentation	According to Fermentation products Ph. Eur.	Conform		Data producer
Identification A	+26,5 - +29,0	Conform	°	Specific optical rotation
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=BY6	Conform		2,5% <i>m/V</i>
Specific optical rotation	+26,5 - +29,0	+28,2	°	8% <i>m/V</i> in HCl 25%; dried
Ninhydrin-positive substances	Conform	Conform		
Impurity B at 570 nm	<=0,4	<0,05	%	
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=1,0	<1,0	%	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	Conform	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,2	%	105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay L-Valine	98,5 - 101,0	99,9	% <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 laboratory Eurofins.

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

02/24/20

Expiration: 05-2022

Conclusion: APPROVED

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