

Certificate of Analysis

Product name: **Argininum apyrogen**
Batch number / Weight: **21L16-B02-217440 / 100 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+25,5 - +28,5	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / <=BY6	Conform		
Specific optical rotation	+25,5 - +28,5	+28,1		
Ninhydrin-positive substances	Conform	Conform	%	
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,10	%	
Sulphated ash	<=0,1	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Arginine	98,5 - 101,0	99,0	%m/m	
Endotoxins	<=6	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

11-05-2022

Expiration: 07-11-2023

Conclusion: APPROVED

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