

## Certificate of Analysis

**Product name:** **Argininum apyrogen**

**Batch number / Weight:** **21F14-B11-213212 / 100 G**

**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		Hygroscopic
Identification A	+25,5 - +28,5	Conform		Specific optical rotation
Identification C	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=BY6	Conform		5% <i>m/V</i>
Specific optical rotation	+25,5 - +28,5	+26,8	Å°	8% <i>m/V</i> in HCl 25%, dried
Ninhydrin-positive substances	Conform	Conform	%	HPLC
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
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	0,49	%	105 °C
Sulphated ash	<=0,1	0,03	%	
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	99,2	% <i>m/m</i>	Dried
Endotoxins	<=6	<6	IU / g	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

28-12-2021

Expiration: 04-02-2024

Conclusion: APPROVED

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