

Certificate of Analysis

Product name: **Arginini hydrochloridum apyr.**

Batch number / Weight: **21F14-B12-217681 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Fermentation	According to Fermentation products Ph. Eur.	Conform		
Identification A	+21,0 - +23,5	Conform	°	
Identification B	Conform	Conform		
Identification E	Conform	Conform	%	
Appearance of solution	Clear / <=BY6	Conform		
Specific optical rotation	+21,0 - +23,5	+22,7	°	
Ninhydrin-positive substances	Conform	Conform		
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
Sulphates	<=300	<300	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,01	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Arginine hydrochloride	98,5 - 101,0	100,0	%m/m	
Endotoxins	<=6,0	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

17-03-2022

Expiration: 16-01-2024

Conclusion: APPROVED

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